SYSTEM 83 PLUS™
(WASHER/DISINFECTOR)

(DOS) OPERATOR'S MANUAL

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SYSTEM 83 PLUS™ (WASHER/DISINFECTOR)

DOS OPERATOR'S MANUAL FOR MODELS:

83 PLUS 2

83 PLUS 9

83 PLUS 10

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INTRODUCTION:

The field of endoscopy has expanded to include every medical discipline, including the field of general surgery. As a result of the development of new diagnostic and treatment techniques, the flexible endoscope has become sophisticated and intricate in design. To provide a flexible endoscope that is safe for reuse, the requirements for reprocessing the endoscope must be understood.

The ***System 83 Plus™ (Washer/Disinfector)*** is intended for the cleaning and high-level disinfection of one or two submersible flexible endoscopes that feature several internal channels that do not contact normally sterile areas of the body (i.e. semi-critical devices). The types of flexible endoscopes for which this device is labeled to reprocess include those that are used to examine, diagnose and treat diseases of the upper and lower GI tract. Examples include flexible colonoscopes, gastroscopes and duodenoscopes.

The flexible endoscope is comprised of an insertion tube, an umbilical cord that attaches to a power source, and a control head that is used to manipulate the distal tip of the insertion tube. Knowing the endoscope manufacturer's requirements for processing a flexible endoscope is important to understanding the synergism of all components used for decontaminating the flexible endoscope so it is "safe for patient use". The quality of the water, temperature, detergent and germicide followed by the number of water rinses and drying of the endoscope all impact the outcome.

The department using flexible endoscopes must establish acceptable standardized reprocessing procedures for decontaminating flexible endoscopes following the patient procedure and prior to reuse. Before processing flexible endoscopes, we recommend you review the processing guidelines published by ***SGNA***, ***APIC***, **and** ***ASGE***.

The ***System 83 Plus™ (Washer/Disinfector)*** is designed to:

- be used in accordance with the reprocessing instructions described in the operator's manual of the endoscope;
- satisfy the label requirements (e.g., time, temperature and number of required terminal water rinses) of all liquid chemical sterilants/disinfectants (LCGs) cleared by the FDA for reprocessing flexible endoscopes (refer to: http://www.fda.gov/cdrh/ode/germlab.html);
- facilitate compliance with published endoscope reprocessing guidelines;
- meet or exceed reprocessing standards established by the SGNA, AORN, APIC, ASGE, CDC and FDA and other endoscope-reprocessing and infection-control organizations (see: http://www.sgna.org for a set of step-by-step reprocessing instructions; and
- standardize the reprocessing protocol, specifically washing, chemical immersion and water rinsing, to improve patient safety and minimize variability inherent to manual reprocessing.
- be used in accordance with the instructions provided in its operator's and service manuals.

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SYSTEM 83 PLUS™ WASHER/DISINFECTOR

WATER QUALITY, FILTRATION AND TEMPERATURE:

Across the United States, the quality of water (e.g., content of sediment and waterborne microorganisms) varies and can affect the plumbing lines, mechanical components of the ***System 83 Plus™ (Washer/Disinfector)***, and the final outcome of the standardized process. Mineral and sediment content in the water supply can leave deposits on the mechanical components of ***System 83 Plus™ (Washer/Disinfector)***, alter the effectiveness of the germicide, and leave debris on the endoscope and internal channels.

Potable water may contain low numbers of resident waterborne microorganisms that under normal conditions are not of clinical concern. However, they can pose a risk of infection when reprocessing flexible endoscopes.

The ***Custom Ultrasonics, Inc. System 83 Plus™ (Washer/Disinfector)*** **requires** the installation of a **5-micron filter** for removing sediment from the water. In addition, an appropriate **0.1 micron bacterial filter** is required after the **5-micron sediment filter**. A **25 micron sediment filter** or an automatic back flush system may be required before the **5-micron sediment filter** where there is a high level of sediment in the water supply. ***Custom Ultrasonics, Inc.*** suggests you consider routinely monitoring the rinse water used during endoscope reprocessing.

Please contact *Custom Ultrasonics, Inc.* for information on acceptable water filter systems and if necessary, a water softener

Water temperature is critical to the process outcome and should be set to 110° Fahrenheit.

The water temperature should not exceed 115° Fahrenheit, nor drop below 105º Fahrenheit.

DETERGENTS:

"Detergents are complex chemicals when dissolved in water in the proper concentration will breakdown and dissolve grease, oil, and other foreign matter, or will break up and suspend these materials in the solution so that they can be removed in the cleaning process."

Available are a variety of detergents for cleaning medical devices. An appropriate detergent is effective and compatible with the 3 minute standardized cleaning phase for ***System 83 Plus™ (Washer/Disinfector).*** It should be low foaming and free rinsing. Custom Ultrasonics recommends using Tergel 800 in our ***System 83 Plus™ (Washer/Disinfector).***

Enzymatic formulations designed to dissolve **protein** contaminants during soaking have a specified dilution rate, immersion time and temperature requirements. The manufacturer's labeling should be reviewed to determine the specifications for effectiveness and compatibility.

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Detergents other than Tergal 800 may be used in the ***System 83 Plus™ (Washer/Disinfector)*** provided they are: (a) specifically formulated for ultrasonic cleaning, (b) compatible with the components of the endoscope and the ***System 83 Plus™ (Washer/Disinfector)*** and (c) for which validated simulated in-use data (e.g., microbiological or equivalent) demonstrate the detergent's effectiveness when used to clean endoscopes during *worst-case* testing conditions.

All tests performed to assess washing effectiveness were performed using Tergal 800, an ultrasonic compatible (alkaline) detergent. This data can be reviewed at www.customultrasonics.com. ***Custom Ultrasonics, Inc.*** has received a few reports that suggest some brands of detergent (e.g., Klen-zyme, Instru-Klenz) do not satisfy all three of these criteria and therefore, is not appropriate for use in the ***System 83 Plus™ (Washer/Disinfector). Contact Custom Ultrasonics, Inc.*** before using a brand of detergent other than Tergal 800. Use of an un-tested detergent is not recommended and may result in ineffective reprocessing or damage to the endoscope and/or System 83Plus™ (Washer/Disinfector).

MECHANICAL ACTION DURING THE *SYSTEM 83 PLUS™ (WASHER/DISINFECTOR)* CLEANING PHASE:

Mechanical scrubbing action, in combination with a warm detergent solution, is necessary during almost every cleaning process. ***System 83 Plus™ (Washer/Disinfector)*** employs a re-circulating pump with high pressure outputs to clean and purge the endoscopes narrow internal channels along with ultrasonic sound waves during the cleaning and water rinsing phases.

The **low intensity, sound waves** of the ***System 83 Plus™ (Washer/Disinfector)*** since 1979 have been found to be compatible with flexible endoscopes, and have shown to achieve a high level of cleaning and rinsing. **Low intensity sound waves** within the solution set into motion molecules in the water and detergent at a very rapid rate creating small bubbles. When these bubbles reach a critical mass, as a result of high and low pressure waves, they **implode** creating a vacuum that removes contaminates from the surfaces of the endoscope, as well as its inaccessible areas and crevices resulting in a clean surface that is necessary before immersion in a liquid germicide. No cases of endoscope damage due to the Ultrasonics provided by ***System 83 Plus™ (Washer/Disinfector)*** have been reported.

Custom Ultrasonics, Inc. uses lower level ultrasonic sound waves as opposed to high level ultrasonic sound waves used in surgical instruments and table top cleaners. Ultrasonic sound waves in combination with Tergal 800 (detergent), and proper water temperature are compatible with flexible endoscopes. The sound waves potentiate the detergent aiding removal of the contaminations from the flexible endoscopes and its removable parts during reprocessing.

System 83 Plus™ (Washer/Disinfector) features "low-pressure" purging outputs designed to irrigate the endoscope's channels.

System 83 Plus™ (Washer/Disinfector) features "high-pressure" purging outputs designed to irrigate the endoscope's narrower and harder-to-reprocess accessory channels such as, the colonoscope's auxiliary water jet channel and the side-viewing duodenoscope's elevator-wire channel.

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TIME REQUIREMENTS FOR THE *SYSTEM 83 PLUS™ (WASHER/DISINFECTOR)* STANDARDIZED PROCESS:

Each phase of the ***System 83 Plus's™ (Washer/Disinfector)*** **standardized and automated process** has been tested, validated, timed and has a proven record of performance since 1979. The **standardized process** has shown to remove, **under worst case scenario simulated in-use testing**, contaminates during cleaning, the microorganisms during immersion in a germicide and residual germicide during rinsing.

Please contact *Custom Ultrasonics, Inc.* for information on our patented testing protocol #6,428,747 and the Summary and Overview for Safety and Effectiveness of the *System 83 Plus™ (Washer/Disinfector)*.

The cycle time of the **standardized process** may vary depending on the length of the immersion time for the germicide and the number of rinses as required in the germicide's labeling.

LIQUID CHEMICAL GERMICIDE ("LCG"):

Custom Ultrasonics, Inc. does not recommend a specific chemical germicide other than to require it be FDA cleared and compatible with the ***System 83 Plus™ (Washer/Disinfector)*** components and flexible endoscopes. "LCG" is used throughout this manual to refer to any FDA-cleared liquid disinfectant/sterilant.

Please contact *Custom Ultrasonics, Inc.* to confirm the germicide you selected is compatible with *System 83 Plus™ (Washer/Disinfector)* and for any additional information as it relates to the use of the germicide (e.g., immersion time and temperature).

The ***System 83 Plus™ (Washer/Disinfector)*** monitors the germicide temperature in the reservoir and as the germicide passes through the internal channels of the endoscope. The temperature is displayed on the LCD Color Monitor for verification.

ENDOSCOPE DRYING AND STORAGE:

Because the internal channels of flexible endoscopes retain water that may contain some level of waterborne microorganisms, **proper drying and storage of the endoscope** is required.

After completion of the **standardized process**, the lumens of a flexible endoscope should be purged with **70% isopropyl alcohol followed by forced air to facilitate drying.**

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STANDARDIZED PROCESS *SYSTEM 83 PLUS™ (WASHER/DISINFECTOR)*:

The ***System 83 Plus™ (Washer/Disinfector)*** offers an automated, validated, standardized and documented process that has been shown to achieve as much as **a 9 log reduction of bioburden** when used in accordance with its labeling, and the labeling of the selected germicide. Depending on the effectiveness of the manual pre-cleaning protocol, a greater log reduction may be achieved.

The ***System 83 Plus™ (Washer/Disinfector)*** is designed to compliment, not replace, manual pre-cleaning.

For each flexible endoscope reprocessed in *System 83 Plus™ (Washer/Disinfector)*, the following print out is provided:

Start:
Day/Date/Month/Year
Flexible Endoscope –Model – Serial Number
Physician Name
Patient Name – ID
Technician Name
Detergent Name
Disinfectant Name
Time Process Started
Wash Time
Rinse Time
Disinfectant Time – Temperature
First Rinse Time
Second Rinse Time
Third Rinse Time
Time Process Completed
Time Duration of the Process

The print-out is comprehensive and it must be visually checked following *each* cycle as a standard operating quality control procedure to ensure all of the reprocessing parameters were met.

It is recommended that a print-out be provided and retained for documentation purposes.

During the wash phase, the one or two endoscope(s) are completely immersed in several gallons of fresh, filtered water mixed with a detergent (e.g., Tergal 800) that is: (a) specifically formulated for ultrasonic cleaning, (b) compatible with the components of the endoscope and the ***System 83 Plus™ (Washer/Disinfector),*** and (c) for which validated simulated in-use microbiological (or equivalent) data are available for review and demonstrate the detergent's effectiveness when used to clean endoscopes during *worst-case* simulated use testing conditions. During the wash phase, the endoscope is exposed to ultrasonic energy and a re-circulating pump irrigates each of the endoscope's channels with detergent.

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During the ***System 83 Plus™ (Washer/Disinfector)*** high-level disinfection phase, one or two endoscope(s) are completely immersed in several gallons of a user-selected liquid chemical sterilant/disinfectant (LCG) cleared by the FDA for the high-level disinfection of endoscopes (see: http://www.fda.gov/cdrh/ode/germlab.html, (2) the temperature of the LCG is elevated, if required. Both the immersion time and temperature of the LCG is monitored and controlled in accordance with its labeling and (3) a re-circulatory pump irrigates each of the endoscope's channels with the LCG. No ultrasonic energy is produced during this phase.

The water rinse phase removes potentially toxic chemical residues from the endoscope's surfaces. The endoscope is rinsed once with fresh, filtered "bacteria-free" water after the wash phase and two or three times after the high-level disinfection phase, depending on the LCG's labeling.

During each water rinse phase: (1) the endoscope is completely immersed in several gallons of fresh, filtered bacteria free rinse water; (2) the endoscope is exposed to ultrasonic energy; and (3) a re-circulating pump irrigates each of the endoscope's channels with fresh, filtered rinse water.

Note: *Failure to immerse the endoscope in the detergent and liquid chemical disinfectant sterilant for the recommended time and temperature and at the appropriate concentration may result in ineffective reprocessing.*

Note: *Air bubbles produced by this air compressor after each reprocessing phase and during 70% isopropyl alcohol rinsing can be used to visually confirm fluid flow through each channel-tubing adapter, as required to ensure reprocessing of each endoscope channel.*

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PHYSICAL DESCRIPTION OF *SYSTEM 83 PLUS™ (WASHER/DISINFECTOR)*

The ***System 83 Plus™ (Washer/Disinfector)*** is a computer controlled mobile, free standing unit with power cord(s), hospital grade electrical plug(s), hot and cold water lines and 2 waste drain hoses per bay. The cabinet is painted carbon steel and the germicide and processing chambers are stainless steel and recessed under a Corian™ countertop. Located on the front of the Corian™ countertop is a keyboard, at the rear a Monitor, printer, hand spray, and a bulkhead for injecting 70 % isopropyl alcohol to facilitate drying the endoscopes. The lids for the processing chamber and germicide reservoir chamber are clear or optional metal lids with clear window insert.

- Lift the lid slowly and rest it against the rear brackets so as not to damage the top and hinges.
- Do not slam or force the lid against the rear brackets as this will damage the hinges and rear brackets.
- Remove any objects (scope adapters) on the countertop before lowering the lid as this will damage hinges and crack the clear top.
- Do not use the rear lid brackets to move the system.
- Do not hang adapters over the outside of the processing chamber.

Available, as an option, is an automatic foot pedal operated lid control for the processing chamber for convenient handling when loading and unloading flexible endoscopes, operating buttons, valves and miscellaneous re-moveable parts.

On the front door panel of ***System 83 Plus™ (Washer/Disinfector)***, there is a switch for the air pump and hand spray. An optional 3rd switch noted **"ERCP"** may be installed if monitoring the flow and pressure through individual channels of flexible endoscopes during reprocessing has been purchased.

Circuit breaker(s), mounted on the <u>right side wall</u> of the cabinet serves as the main power switch for the *System 83 Plus™ (Washer/Disinfector)*. The circuit breakers should remain in the "ON" position, and turned "OFF" by a qualified technician before performing service or maintenance on *System 83 Plus™ (Washer/Disinfector)*.

The ON/OFF button for *System 83 Plus™ (Washer/Disinfector)* is located on the computer inside the front door of the cabinet.

ELECTRICAL REQUIREMENTS:

The *System 83 Plus™ (Washer/Disinfector)* requires a **DEDICATED 120 Volt, 20-amp 60Hz** receptacle. **GFI receptacle(s) are not recommended** since the ***System 83 Plus™ (Washer/Disinfector)*** contains an electrostatic isolation transformer that reduces leakage to ground and may trip the hospital breaker, the system's breaker or both.

NOTE: Do not connect or operate ***System 83 Plus™ (Washer/Disinfector)*** using an emergency generator because it may create current surges that will damage computer components.

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PLUMBING REQUIREMENTS:

The hot and cold water supply lines provided by the facility for ***System 83 Plus™ (Washer/Disinfector)*** may be **½" or ¾" copper** with shut off valves having ¾" male garden hose adapters. The number of hot and cold water lines required to operate the ***System 83 Plus™ (Washer/Disinfector)*** is based on the number and type of independently operated systems selected. For example, an 83+2 model requires a hot and cold line.

The required water pressure is **40 to 50 PSI** (pounds per square inch) with a flow rate of between **8-10 GPM (gallons per minute)**. If the water pressure **exceeds 50 PSI, a pressure reducer valve must be installed to safely operate the *System 83 Plus™ (Washer/Disinfector)***. Water temperature should be **110 degrees F** and can not exceed **115 degrees F or drop below 105 degrees F**. If plumbing code requires a vacuum breaker, install only a **non-atmospheric vacuum breaker**. A significant drop in the flow rate may indicate a clogged filter that requires replacement.

WASTE DRAIN REQUIREMENTS:

"**Standpipe"** - 2 inches in diameter and minimum 18" above floor level and/or "**Washer Box**"- configured for water supply and drain per Bay.

COMPUTER HARDWARE:

System 83 Plus™ (Washer/Disinfector) contains an IBM compatible CPU, Keyboard, LCD high resolution color monitor and printer. The keyboard and monitor have protective covers.

The keyboard protective cover should be cleaned periodically to ensure every key is visible. Clean the LCD Color monitor and protective cover with a soft cloth that will not scratch the glass like finish. The printer should be checked periodically for paper.

Manuals: The ***System 83 Plus™ (Washer/Disinfector)*** operator's and service manuals are provided with each newly purchased system.

Additional Manuals are available for purchase: The Operator's Manual part #13029 Bio-Medical Manual part #13025.

INSTALLATION:

System 83 Plus™ (Washer/Disinfector) should be inspected upon receipt for damage, and compare items received to the bill of lading. The healthcare facility should move the System to the designated area for installation or a secure area if installation requirements are not completed.

System 83 Plus™ (Washer/Disinfector) **cannot be operated until the arrival of the factory technician for In-Service Training.**

IN-SERVICE TRAINING PROGRAM:

Following delivery of ***System 83 Plus™ (Washer/Disinfector),*** the medical facility must schedule a date for the training of Operating and Bio-medical personnel by a ***Custom Ultrasonics, Inc.*** technician. The training date for the personnel cannot be scheduled until ***Custom Ultrasonics, Inc.*** has a complete listing of all the facility's flexible endoscopes, and the technician has all the required adapters for the listing of

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endoscopes. **The LCG selected for use** in ***System 83 Plus™ (Washer/Disinfector)*** **must be available** at the time of training session.

The **In-Service Training Program** is a day and a half in length unless prior arrangements are made. During the In-Service Training, personnel will operate the ***System 83 Plus™ (Washer/Disinfector)*** and match adapters to the individual flexible endoscope models in inventory at the time of the In-Service Training and to the different pressure outputs of the purging manifold for ***System 83 Plus™ (Washer/Disinfector).***

For personnel assigned the responsibility for reprocessing flexible endoscopes, attendance will assure all sections of the training program are reviewed and the handouts, charts and instructions are understood and retained for reference. Maintenance and Bio-Medical personnel is required to attend the training on routine required maintenance procedure, the operating software program and the software diagnostic service program.

***Retraining of personnel and for newly assigned personnel is available for an additional charge after initial training has been completed.**

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SYSTEM 83 PLUS™ (WASHER/DISINFECTOR)

DOS OPERATOR'S MANUAL FOR MODELS:

83 PLUS 2

83 PLUS 9

83 PLUS 10

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SYSTEM 83 PLUS™ (WASHER/DISINFECTOR)

To operate ***System 83 Plus™ (Washer/Disinfector)*** the front cabinet door must be opened, and the **ON/OFF** switch on the computer engaged. Allow the computer to "**Boot Up**" and the **Main Menu Bar** will appear.

MAIN MENU BAR

RUN CU--MASTER DATA--REPORTS--MISC--DAY/MO/TIME/YEAR

BEFORE OPERATING *SYSTEM 83 PLUS ™(WASHER/DISINFECTOR)*, PERFORM THE FOLLOWING:

Check the time and date.
Check the temperature of the germicide.
Check the concentration of the germicide in the reservoir.
Confirm the germicide level **(volume)** is sufficient.

Check the time and date in the upper right hand corner of the Menu Bar. If the time or date is incorrect, **hold down the (ALT) and (X) keys.**

To adjust the time at the prompt, C:\CUversion # or A:\CUversion #, type the word TIME and press the (ENTER) key. Enter time using 24-hour clock system (1 PM =13:00:00).

Example:

C:\CU071097>time.
Current time is 14:35:15.05p.
Enter new time: 12:35:15.05p.
Press the **(ENTER)** key.

To adjust the date at the prompt, C:\CUversion # or A:\CU version #, type the word DATE and press the (ENTER) key, enter the date in the format as shown on the screen.

Example:

C:\CU071097>date.
Current date is day – Mon.10-19-2005.
Enter new date Fri. 11-4-2005.
Press the **(ENTER)** key.

Reboot the computer by simultaneously pressing **(Ctrl) (Alt) (Del) keys.**

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MAIN MENU BAR

RUN CU--MASTER DATA--REPORTS--MISC--DAY/MO/TIME/YEAR

Hold down the **(ALT)** key and **press the letter (U) key. (RUN CU)**, For *System 83 Plus™2*, "Pre-Processing Guidelines" will appear. After completing the pre-processing guidelines for the flexible endoscope, press the (**ENTER)** key and the **Standard Menu Bar** will appear. **(See example below).**

STANDARD MENU BAR

(F1) PATIENT **(F2)** SYSTEM DATA **(F4)** SPECIAL **(F6)** WASH **(F8)** WASH & D/S/P **(F10)** MAIN

For *System 83Plus™9* on pressing (**ALT) and (U)** keys, two screens will appear **BAY 1** and **BAY 2. Highlight either BAY with the arrow key and press (ENTER).** The pre-processing guidelines will appear and, on completion of the pre-processing guidelines, press **(ENTER). Highlight the next BAY with the arrow key and press (Enter),** the pre-processing guidelines will appear and on completion press **(ENTER).**

PROGRAM MENU

SYSTEM 83 PLUS™(WASHER/DISINFECTOR) **FUNCTION KEYS**

The different functions performed by *System 83 Plus™(Washer/Disinfector)* are controlled by a licensed, copyrighted software program that is initiated by pressing **Function Keys** across the top of the Keyboard **(Example (F1))**.

CHANNEL MONITORING

For systems equipped with this feature 10 channel monitoring lights will appear when the process is initiated to confirm flow through the internal channels of the endoscope. If a light appears during the process, *System 83 Plus™(Washer/Disinfector)* will shut down – **(F1) Channel Error** – will appear on the monitor and remain until the cause for the light to appear is determined. Press **(F1)** when the problem is resolved.

STANDARD MENU SCREEN

(F1) PATIENT **(F2)** SYSTEM DATA **(F4)** SPECIAL **(F6)** WASH **(F8)** WASH &D/S/P **(F10)** MAIN

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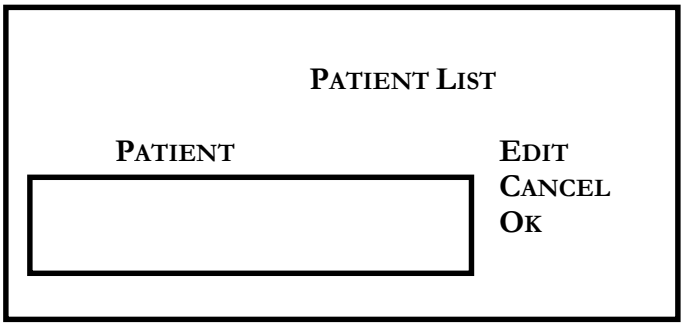
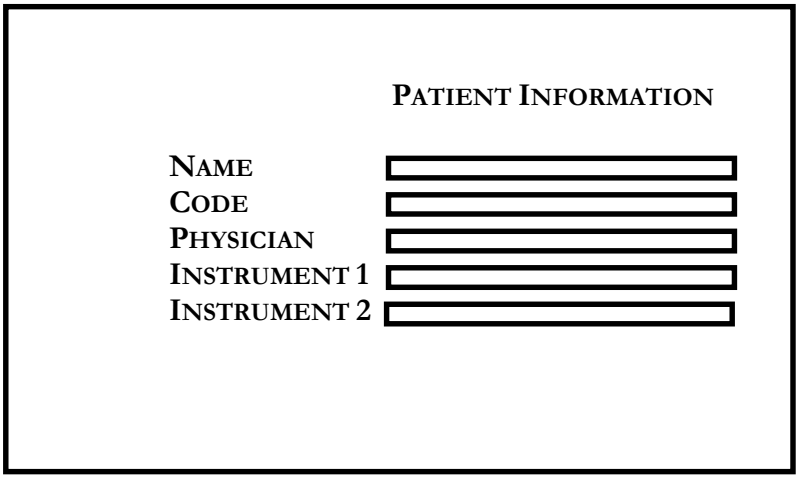
(F1) PATIENT DATA:

Only before and during the standardized process can patient information be entered. Press (**F1) to enter patient data**. The screen below will appear on the monitor.



Press the **(ALT) and (E) key (edit**). Press the **(ALT) and (C) key** (**cancel**) and the **(ALT) and (O) key** (**correct**)

On pressing the (**ALT) and (E) keys the following display will appear:**



Use the **(TAB) Key** on the **keyboard** to highlight each entry and type:

Patient's Name.
Patient's Code.
Physician's Name press **(ENTER)** type name press **(ENTER)**.
Instrument (1) press **(ENTER)** type name press **(ENTER)**.
Instrument (2) press **(ENTER)** type name press **(ENTER)**.
Store in memory press the **(ALT) (O)** keys.

FOR A SECOND PATIENT WITH 1 OR 2 ENDOSCOPES:

Press the **(ALT) and (E)** keys.
Repeat the same steps for one patient.
Store in memory press the **(ALT) and (O) Keys.**

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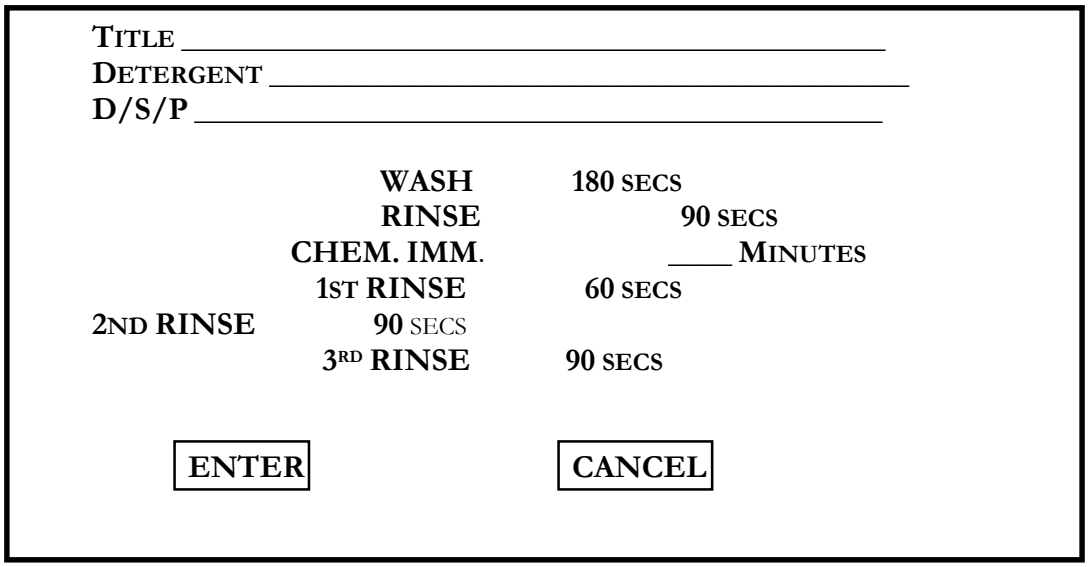
(F2) SYSTEM DATA:

On pressing function key (**F2**) the screen below will appear. Using the **(TAB)** key, tab down to enter the name of the hospital, detergent and germicide. **When changing the detergent or the germicide, it is important to enter the new name and contact *Custom Ultrasonics, Inc.* for a disk to reset the products parameters.**



NOTE: THE STANDARDIZED TIMES FOR THE WASH –RINSE -1ST RINSE, -2ND RINSE AND 3RD RINSE CAN NOT BE CHANGED. THEY ARE THE ESTABLISHED TIMES FOR THE AUTOMATED, VALIDATED, STANDARDIZED AND DOCUMENTED PROCESS FOR REPROCESSING FLEXIBLE ENDOSCOPES.

During the In-Service Training, the approved trade name and immersion time for the germicide is entered into the software. **This time can not be decreased, BUT can be increased. Tab** down to increase time. (If disinfectant brand is going to be changed, contact CU for a new Disk).

- Note the expiration date of the disinfectant and replacement.

To exit, press the **(ALT) and (O) keys**.

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(F6) WASH (THIS CYCLE DOES NOT INCORPORATE A CHEMICAL DISINFECTANT PHASE):
On pressing function key **(F6),** the flexible endoscope(s) will be cleaned and rinsed. Warm water at **110° degrees Fahrenheit** and a bolus of concentrated detergent are introduced into the processing chamber. When the liquid level reaches the controlled level, the wash cycle begins for a standardized period of time. On completion, the endoscope channels are purged of liquid and the processing chamber drained. Rinse water is introduced to remove residual detergent and contaminants for an established time period. The system drains completing the wash program.

Detergents can be introduced manually or automatically.

When the wash program is complete, the LCD Monitor screen will display (F2)-Print Results (F3) Continue/ Save/Clear/Patient Data.

On pressing (**F2),** a printed report is generated. Pressing (**F3)** following the printing of the report will store the patient information report in memory, if equipped with a Hard Drive. Pressing (**F3)** will bypass the printing of a report and return the screen back to the standard menu.

(F8) WASH AND (D/S/P):
The (**F8)** program is an automated, validated and standardized wash, rinse, high-level disinfect program with a double or triple rinse based on the germicide label. At the completion of this program, the flexible endoscope is high level disinfected and patient safe.

- Double check the immersion time programmed into the software.

On pressing (**F8)**, a message will appear at the base of the LCD Color Monitor. (**F1) Check Disinfectant Level.**

System 83 Plus™ (Washer/Disinfector) is equipped with sophisticated technology for monitoring the germicide's temperature in its reservoir, during the reprocessing of the endoscope in the processing chamber and as the germicide passes through the internal channels of the flexible endoscope. The temperatures are displayed on the LCD Color Monitor.

Processing of the endoscope will not begin until the preset (start up) temperature for the germicide is achieved. The temperature is preset by ***Custom Ultrasonics, Inc.*** during the In-Service Training in accordance with the product's temperature claim.

In the event the preset disinfectant temperature is below temperature on pressing **(F1)**, an error is displayed on the LCD Color Monitor.

"Minimum reservoir temperature not achieved "

To protect the disinfectant from exceeding the temperature label claim for the germicide, a maximum abort error is programmed in the software.

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"System aborted due to temperature level"

After checking the concentration and level of the disinfectant in the reservoir and on pressing (F1), the process is initiated. The flexible endoscopes will be cleaned, rinsed, high level disinfected and double or triple rinsed in accordance with the germicide label.

On completion the of the final rinse of the (**F8)** program, the process tracking arrow on the VGA Color Monitor will point to **"COMPLETE"** and a Menu Bar will appear.

- On completion of the process, check the print out to assure process parameters were achieved.

MENU BAR

(F1) PATIENT DATA **(F2)** PRINT RESULTS **(F3)** CONTINUE/SAVE/CLEAR DATA

PRESS (F1) REVIEW SCREEN BELOW **PRESS (F2) PRINT SCREEN BELOW**

HOSPITAL NAME

PATIENT: JOHN DOE ID: 123-45-6789
PHYSICIAN: DR. SMITH
INSTRUMENTS: GIF100
SYSTEM 83+

STARTED, FRI., MAY 04 11:18:44 2000
ULTRASONIC WASH FOR 180 SECONDS WITH **DETERGENT NAME**
RINSE FOR 90 SECONDS
EXPOSED TO (**GERMICIDE NAME**) FOR ___MIN. AT ___ CEL.
1ST RINSE FOR 60 SECONDS
2ND RINSE FOR 90 SECONDS
3RD RINSE FOR 90 SECONDS
COMPLETED, FRI., MAY 4 11:56:49 2000

PRESS (F2) CONTINUE/CLEAR

PRESS (F3) CONTINUE/SAVE/CLEAR (FOR SYSTEMS WITH A DATA BASE)

THE PROCESS TRACKING ARROW WILL POINT TO SELECT

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(F10) MAIN:

System 83 Plus™ (Washer/Disinfector) is available with two independently operated bays within a single cabinet that are identified on the LCD Color Monitor screen as **BAY 1 and BAY 2** on pressing (**F10)**.

To monitor the status of either BAY during the standardized process, highlight **(for example BAY 1)** using the curser on the keyboard and press (**ENTER).** To go back to the monitor screen with BAY 1 and BAY 2 **press (F10)**

IMPORTANT INFORMATION

ONCE A PROGRAM IS INITIATED, IT CANNOT BE ABORTED. THE PROGRAM MUST RUN TO COMPLETION.

IF A **SYSTEM FAULT** OCCURS, THE ARROW ON THE DIAL WILL MOVE TO **COMPLETE** AND A SCREEN PROMPT IDENTIFYING THE ERROR WILL APPEAR ON THE MONITOR. DIRECTIONS WILL APPEAR ON THE SCREEN TO CLEAR THE FAULT. IF ASSISTANCE IS REQUIRED, MAKE NOTE OF THE PROBLEM BEFORE SPEAKING TO A QUALIFIED TECHNICIAN WHO WILL GUIDE YOU ON MAKING THE NECESSARY CORRECTION.

CAUTION: IF AN ERROR OCCURS, THE SELECTED PROCESS WILL NOT HAVE BEEN COMPLETED. THE OPERATOR MUST DETERMINE THE STEPS TO FOLLOW TO COMPLETE THE SELECTED PROCESS AFTER ADDRESSING THE SYSTEM ERROR.

STANDARD MENU BAR

(F1) PATIENT **(F2)** SYSTEM DATA **(F4)** SPECIAL **(F6)** WASH **(F8)** WASH & D/S/P **(F10)** MAIN

(F4) SPECIAL PROGRAM SCREEN:

On pressing function key (**F4)**, a new menu bar appears that features the **SPECIAL PROGRAMS** for *System 83 Plus™ (Washer/Disinfector)* as shown below.

SPECIAL MENU BAR

(F1) PATIENT **(F2)** SYSTEM DATA **(F3)** STANDARD **(F4)** D/S/P **(F5)** EMPTY **(F6)** PURGE **(F7)** RETURN D/S/P **(F10)** MAIN

(F3) STANDARD PROGRAM SCREEN:

After completing any of the functions as shown on the above Menu Bar, pressing **(F3)** will return back to the operating menu as shown below.

(F1) PATIENT **(F2)** SYSTEM DATA **(F4)** SPECIAL **(F6)** WASH **(F8)** WASH & D/S/P **(F10)** MAIN

SPECIAL MENU BAR

(F1) PATIENT **(F2)** SYSTEM DATA **(F3)** STANDARD **(F4)** D/S/P **(F5)** EMPTY **(F6)** PURGE **(F7)** RETURN D/S/P **(F10)** MAIN

NOTE: DO NOT NEUTRALIZE CHEMICAL GERMICIDE IN RESERVOIR PERFORM ONLY IN PROCESSING CHAMBER.

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(F4) DOUBLE RINSE OR TRIPLE RINSE:

This program is designed to high-level disinfect and rinse flexible endoscopes in the morning following storage before patient procedures as may be recommended.

This program is designed to high level disinfect flexible endoscopes that have been manually pre-cleaned, in accordance with **SGNA guidelines.**

After checking the germicide concentration and volume (level) in the germicide reservoir press (**F1) to initiate the program**. On completion of the disinfect and rinse program, the color monitor will display:

> **NOTE**: ONLY BEFORE AND DURING THE DISINFECT AND RINSE PROCESS CAN PATIENT INFORMATION BE ENTERED.

(F1) PATIENT DATA **(F2) PRINT RESULTS**

Press (**F3)** to return to the **Standard Menu Bar**

(F5) EMPTY (PROCESSING CHAMBER):

This program will drain the processing chamber should there be a **Fault** in the automated process requiring the standardized process be repeated. When an error occurs, the processing chamber must be emptied and the error or fault corrected.

To empty the processing chamber press (**F5)**, allow the chamber to empty and on completion press (**F1) Stop Maintenance** as shown on the LCD Color Monitor

To exit (**F5)** and **Special Menu Bar** press (**F3)**

(F6) PURGE:

All liquid germicides have an expiration date either in days, usage or potency. Refer to the germicides label for instructions. When the reuse life of the germicide has expired in ***System 83 Plus™ (Washer/Disinfector)***, the germicide must be purged from the system. If neutralizing chemical is required, neutralize chemical in processing chamber, not reservoir. Please contact ***Custom Ultrasonics, Inc.*** with any questions.

1. Connect a minimum of three (3) adapters to the purging manifold starting from the right to left in consecutive order. If the ***System 83 Plus™ (Washer/Disinfector)*** is equipped with high pressure ports, make certain the right high pressure port has an adapter and is laying on the floor of the processing chamber.

2. Press **(F6)** and the germicide will be pumped from its reservoir into the processing chamber and into the hospital drain line. Keep chamber lids closed during purging of the system.

3. When all chemical has drained out of the machine, clean the reservoir and processing chamber with a small amount of chlorine based agent such as Comet or Ajax and a soft wet cloth (Lint Free).

4. After cleaning the chamber, make certain to rinse the entire cleaning agent out of the chamber with a clean cloth and a bowl of fresh water. **(If the machine is equipped with hand rinse sprayer, use sprayer to rinse down chamber.)**

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5. Once all the rinse water has drained out of the reservoir, pour one (1) quart of newly activated chemical agent into the reservoir and allow it to drain into the processing chamber.

6. When no chemical solution remains in the reservoir or the processing chamber, Press (**F1) Stop Maintenance.** Use a lint free cloth to dry the reservoir chamber.

7. The reservoir is now ready to be filled with 8 gallons of the germicide.

8. To exit the **Special Menu Bar** and return to the **Standard Menu Bar**, Press **(F3) Standard**.

9. Clean the Corian™ top, machine lids, keyboard cover, monitor cover and exterior of the cabinet, with a non-abrasive cleaner disinfector.

(F7) RETURN D/S/P (RETURNS THE DISINFECTANT TO RESERVOIR):

This special program will return the germicide from the processing chamber to its reservoir**.** This program will be required should *System 83 Plus™ (Washer/Disinfector)* shut down during the germicide immersion phase. The germicide must be returned to its reservoir before initiating any program.

NOTE: BEFORE PRESSING (F7), CHECK AND BE ABSOLUTELY CERTAIN THAT YOU ARE RETURNING THE GERMICIDE AND NOT WATER THAT MAY BE IN THE PROCESSING CHAMBER.

1. Press (**F7) to return** the germicide. The solution will be transferred from the processing chamber the reservoir.

2. When there is no germicide in the processing chamber and the **flow light** on the above right side of the screen is **OFF,** press (**F1) Stop Maintenance**.

3. To exit the **Special Menu Bar** and return to the **Standard Menu Bar**, **Press (F3) Standard**.

(F10) MAIN:

The **(F10)** key on the **Special Menu Bar** only applies to *System 83 Plus™ 9 (Washer/Disinfector)* and changes the monitor screen to display BAY 1 and BAY 2.

End of Day Procedure:

At the end of each day, the System 83 Plus must be turned off.

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DATABASE INPUT INFORMATION

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COMPUTER DATABASE

The **DATABASE** is designed to store information on a hard drive that can be downloaded on a floppy disk for backup. Certain information must be typed before initiating each cycle. The computer will not accept the information once the cycle is complete.

MAIN MENU BAR

RUN CU--MASTER DATA—REPORTS—MISC--DAY/MO/TIME/YEAR

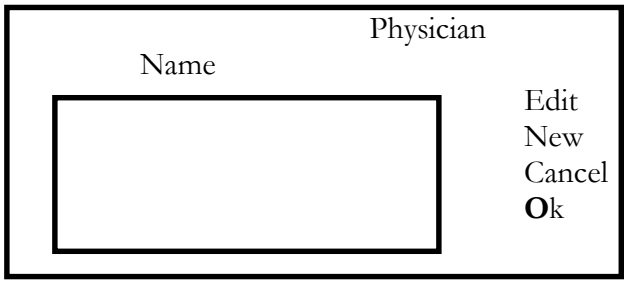
To Input New Physician Names: Press the **(ALT) and (M) keys** simultaneously and the following box will appear:

FIGURE 1

Use the arrow key to highlight "Physicians" and press **(ENTER).**

Press the **(ALT) and (W) keys** simultaneously and the following box will appear:

FIGURE 2



Type the physician's name and press **(ENTER)**. If it was done correctly, the doctor's name should appear in the box. If desired, in the software is a section for notes on the selected physician.

Press the **(ALT) and (O) keys** simultaneously to close the box.

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Changing the name of any physician will corrupt the data base. If the name is incorrect or the person is no longer available, go to the "active/Inactive" box, change to "inactive", save and go to Alt W to re-enter the new or corrected data.

TO INPUT NEW INSTRUMENTS:
From the **Main Menu Bar** press the **(ALT) and (M) keys** for "**Master Data**" menu and box Figure 1 will appear.

- Use the arrow keys to highlight "Instruments" press (**ENTER)**.
- Press (**ALT) and (W) keys** and box Figure 7 will appear.
- Type the name of the instrument and press (**ENTER)**.
- Press the (**ALT) and (O) keys** simultaneously to close the box.

Changing the name of any instrument will corrupt the data base. If the name is incorrect or the item is no longer available, go to the "active/Inactive" box, change to "inactive", save and go to (ALT) and (W) to re-enter the new or corrected data.

TO INPUT DETERGENTS: Contact CU for Replacement Disk!

TO INPUT LIQUID CHEMICAL STERILANT NAMES: Contact CU for Replacement Disk as times and temperatures need to be adjusted!

MAIN MENU BAR
RUN CU--MASTER DATA—REPORTS—MISC--DAY/MO/TIME/YEAR

The **Report Menu** provides the capability to generate a report for reviewing reprocessing cycles between designated dates. Otherwise, if no dates are designated, a complete report is generated for all reprocessing cycles performed.

- Press the (**ALT) and (R) keys** simultaneously.
- Use the arrow keys to highlight "**SET DATE** and press (**ENTER).**
- Type -**mm/dd/yyyy** - Tab down type **mm/dd/yyyy.**
- Press the (**ALT) and (O) keys** simultaneously for **OK.**

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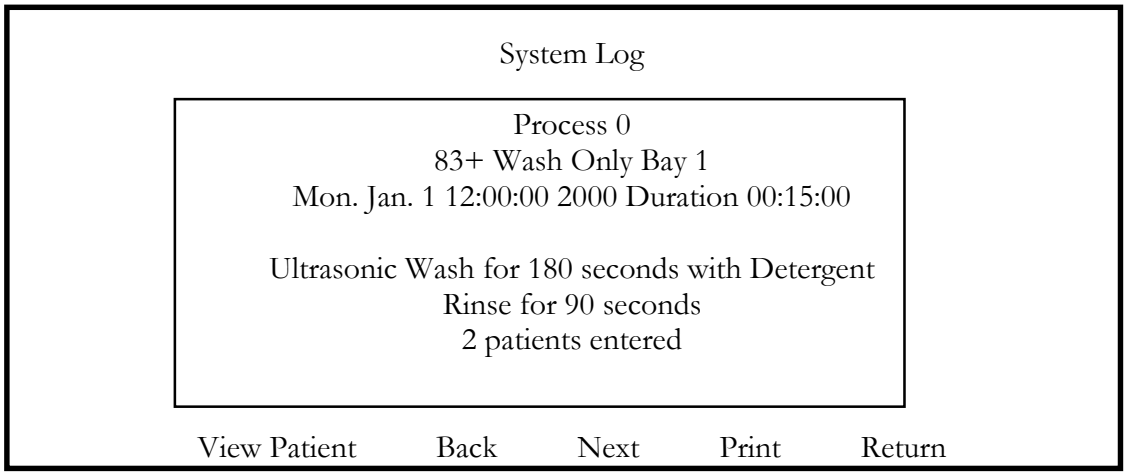
SYSTEM LOG OPERATIONS:

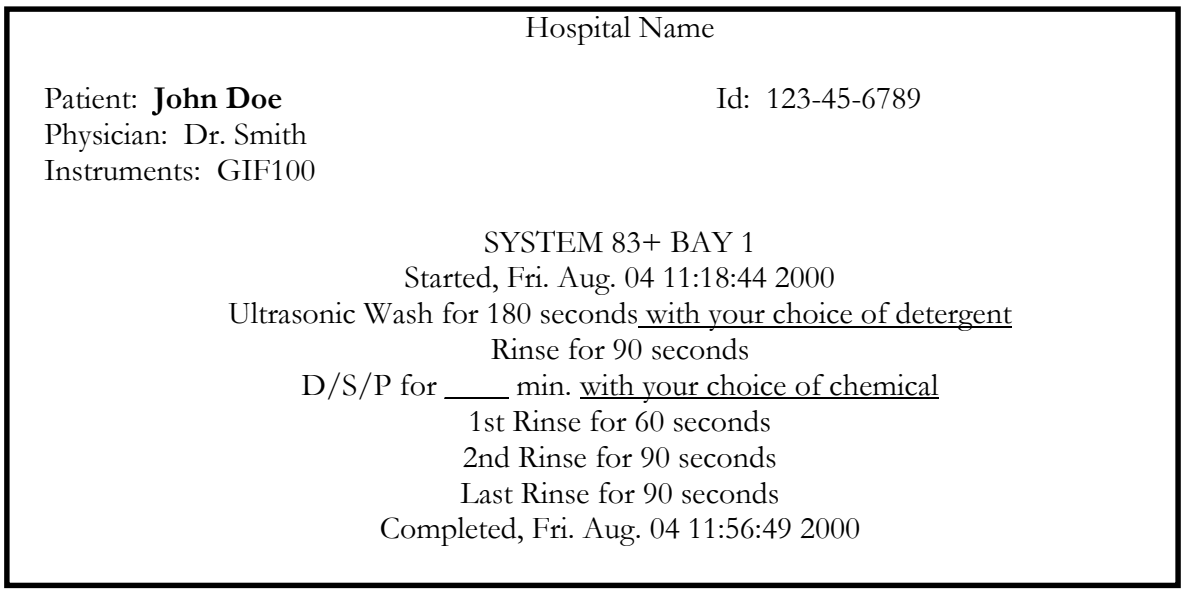
The "System Log" database provides information on the system, instruments and patients. To enter "System Log", press the (**ALT) and (R) keys** simultaneously and use the arrow keys to highlight "System Log". On pressing (**ENTER),** the screen below will appear. To view the 5 boxes in the System Log, tab down until the desired box is highlighted.

FIGURE 3



Highlighting "**View Patient**" will bring up the patient menu Figure 4. Highlighting "**Back**" allows the operator to view the patient before **John Doe** and "**Next**" the patient after **Joe Doe**.

FIGURE 4


Hospital Name
Patient: John Doe
Id: 123-45-6789
Physician: Dr. Smith
Instruments: GIF100
SYSTEM 83+ BAY 1
Started, Fri. Aug. 04 11:18:44 2000
Ultrasonic Wash for 180 seconds with your choice of detergent
Rinse for 90 seconds
D/S/P for ____ min. with your choice of chemical
1st Rinse for 60 seconds
2nd Rinse for 90 seconds
Last Rinse for 90 seconds
Completed, Fri. Aug. 04 11:56:49 2000

Press "**Return**" for the main database screen.

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PRINT SYSTEM LOG:

Press the (**ALT) and (R) keys** simultaneously; highlight "Print Log" and then press (**ENTER)**. The print function allows you to print a hard copy of the patient/instrument information. See Figure 9.

EXPORT DATA FUNCTION:

"Export Data" allows the operator to export data in ASCII format (American Standard Computer Information Interface) for use in other database programs and text files. To enter this function, press the (**ALT) and (R) keys** simultaneously, highlight "Export Data" and press (**ENTER)**. A file name will appear on the monitor. Press (**ENTER)** to accept or enter another file name.

BACKUP DATA FUNCTION:

"Backup Data" saves information in a separate file to ensure accurate records. Press the (**ALT) and (R) keys** simultaneously, scroll down to "Backup Data" press (**ENTER)**. The screen should go blank for an instant. After that the backup is complete. The Facility must have a form of Backup e.g., (Paper printout, disk or CD, or additional Hard Drive).

MISCELLANEOUS MENU ITEMS:

These functions, with the exception of the Service Program, are not available without the use of the password. To access the Service Program press the (**ALT) and (C) keys** simultaneously, highlight service and press (**ENTER)**.

Arrow across the menu to Digital I/O Test and press (**ENTER)**.

***See Bio-medical Maintenance Manual.

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OPERATING INSTRUCTIONS QUICK REFERENCE SHEETS

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COMPUTER OPERATING INSTRUCTIONS FOR SYSTEM 83 PLUS™ 2 (SINGLE BAY)

STEP 1: Entire system is turned "On" by opening front door of unit and engaging On/Off switch on CPU located in lower right hand corner. Allow the computer to perform the "Boot Up" procedure. When the computer is ready, a gray/blue **MASTER MENU** screen will appear.

STEP 2: Hold down the **ALT KEY** and press the "**U**" **KEY** to start the program.

STEP 3: A blue list of **"Pre-Processing Guidelines"** will appear. Review the necessary steps for preparing your instrument for reprocessing. Press **ENTER**. The standard screen will appear. At the bottom of the screen a **"Blue Menu Bar"** will display a selection of options using the "F#" keys. F1- Patient Data, F2- System Data, F4- Special, F6- Wash, F8- Wash & D/S/P.

STEP 4: Select the desired function: To Wash & Disinfect, Press **F8** (F8 WASH & D/S/P). Check level of Chemical Reservoir, Press **F1** to continue. **Add 3 oz**. of detergent to processing chamber as it fills with water.

STEP 5: When PROCESSING CHAMBER is full and circulation pump starts purging liquid through the adapters, watch for air bubbles to pass through the SCOPE ADAPTERS, this will ensure flow through the adapters.

STEP 6: If you wish to enter Patient Information: Press **F1**, a menu box will appear. To input information, hold down the **ALT KEY** and press the "**E**" **KEY** simultaneously. A new menu box will appear.

A. Type in "Patient Name". Press **TAB (↔)**.

B. Type in "Patient Code". Press **TAB (↔)**.

C. Type in "Physician Name". Press **TAB (↔)**.

D. Type in "Instrument". Press **TAB (↔)**.

E. Repeat step (D.) if there are two instruments for one patient.

F. Hold down the **ALT KEY** and press the "**O**" **KEY**.

G. Repeat STEP 6 for additional patient and scope number 2.

H. Hold down the **ALT KEY** and press the "**O**" **KEY** to return to standard screen.

STEP 7: Upon completion of cycle, Press **F2** to print results and Press **F3** continue, save/clear data and return to standard screen.

STEP 8: Alcohol purge scopes, 25cc one scope, 50cc two scopes. Follow "Alcohol Purging" instructions in the manual.

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COMPUTER OPERATING INSTRUCTIONS FOR SYSTEM 83 PLUS™ 2 D.T. (SINGLE BAY)

STEP 1: Entire system is turned "On" by opening front door of unit and engaging On/Off switch on CPU located in lower right hand corner. Allow the computer to perform the "Boot Up" procedure. When the computer is ready, a gray/blue **MASTER MENU** screen will appear.

STEP 2: Hold down the **ALT KEY** and press the "**U**" **KEY** to start the program.

STEP 3: A blue list of **"Pre-Processing Guidelines"** will appear. Review the necessary steps for preparing your instrument for reprocessing. Press **ENTER.** The standard screen will appear. At the bottom of the screen a **"Blue Menu Bar"** will display a selection of options using the "F#" keys. F1- Patient Data, F2- System Data, F4- Special, F6- Wash, F8- Wash & D/S/P.

STEP 4: Select the desired function: To Wash & Disinfect, Press **F8** (F8 WASH & D/S/P). Check level of Chemical Reservoir, Press **F1** to continue. Three (3) ounces of detergent will be automatically injected into the processing chamber.

STEP 5: When PROCESSING CHAMBER is full and circulation pump starts purging liquid through the adapters, watch for air bubbles to pass through the SCOPE ADAPTERS, this will ensure flow through the adapters

STEP 6: If you wish to enter Patient Information: Press **F1**, a menu box will appear. To input information, hold down the **ALT KEY** and press the "**E**" **KEY** simultaneously. A new menu box will appear.

A. Type in "Patient Name". Press **TAB (↔)**.

B. Type in "Patient Code". Press **TAB (↔)**.

C. Type in "Physician Name". Press **TAB (↔)**.

D. Type in "Instrument". Press **TAB (↔)**.

E. Repeat step (D.) if there are two instruments for one patient.

F. Hold down the **ALT KEY** and press the "**O**" **KEY**.

G. Repeat STEP 6 for additional patient and scope number 2.

H. Hold down the **ALT KEY** and press the "**O**" **KEY** to return to standard screen.

STEP 7: Upon completion of cycle, Press **F2** to print results and Press **F3** continue, save/clear and return to standard screen.

STEP 8: Alcohol purge scopes, 25cc one scope, 50cc two scopes. Follow "Alcohol Purging" instructions in the manual.

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COMPUTER OPERATING INSTRUCTIONS FOR SYSTEM 83 PLUS™ 2 DATABASE (SINGLE BAY)

STEP 1: Entire system is turned "On" by opening front door of unit and engaging On/Off switch on CPU located in lower right hand corner. Allow the computer to perform the "Boot Up" procedure. When the computer is ready, a gray/blue **MASTER MENU** screen will appear.

STEP 2: Hold down the **ALT KEY** and press the "**U**" **KEY** to start the program.

STEP 3: A blue list of **"Pre-Processing Guidelines"** will appear. Review the necessary steps for preparing your instrument for reprocessing. Press **ENTER.** The standard screen will appear. At the bottom of the screen a **"Blue Menu Bar"** will display a selection of options using the " F# " keys. F1- Patient Data, F2- System Data, F4- Special, F6- Wash, F8- Wash & D/S/P.

STEP 4: Select the desired function: To Wash & Disinfect, Press **F8** (F8 WASH & D/S/P). Check level of Chemical Reservoir, Press **F1** to continue. Three (3) ounces of detergent will be automatically injected into the processing chamber.

STEP 5: When PROCESSING CHAMBER is full and circulation pump starts purging liquid through the adapters, watch for air bubbles to pass through the SCOPE ADAPTERS, this will ensure flow through the adapters

STEP 6: If you wish to enter Patient Information: Press **F1**, a menu box will appear. To input information, hold down the **ALT KEY** and press the "**E**" **KEY** simultaneously. A new menu box will appear.

A. Type in "Patient Name". Press **TAB (↔)**.

B. Type in "Patient Code". Press **TAB (↔)**.

C. Press **ENTER.** Use arrow keys **(·)** to highlight "Doctors Name." Press **ENTER.** Press **TAB (↔)**.

D. Press **ENTER**. Use arrow keys **(·)** to highlight "Instrument." Press **ENTER.** Press **TAB (↔)**.

E. Repeat step (D.) if there are two instruments for one patient.

F. Hold down the **ALT KEY** and press the "**O**" **KEY**.

G. Repeat STEP 6 for additional patient and scope number 2.

H. Hold down the **ALT KEY** and press the "**O**" **KEY** to return to standard screen.

STEP 7: Upon completion of cycle, Press **F2** to print results and Press **F3** continue, save/clear and return to standard screen.

STEP 8: Alcohol purge scopes, 25cc one scope, 50cc two scopes. Follow "Alcohol Purging" instructions in the manual.

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COMPUTER OPERATING INSTRUCTIONS FOR SYSTEM 83 PLUS™ 9 (DOUBLE BAY) FOR SYSTEM 83 PLUS™ 10 (TRIPLE BAY)

STEP 1: Entire system is turned "On" by opening front door of unit and engaging On/Off switch on CPU located in lower right hand corner. Allow the computer to perform the "Boot Up" procedure. When the computer is ready, a gray/blue **MASTER MENU** screen will appear.

STEP 2: Hold down the **ALT KEY** and press the "**U**" **KEY** to start the program.

STEP 3: The screen will be divided into two or more bays, highlight the desired bay by using the **ARROW KEYS < >** to scroll between the bays. Press **ENTER**.

STEP 4: A blue list of **"Pre-Processing Guidelines"** will appear. Review the necessary steps for preparing your instrument for reprocessing. Press **ENTER.** The standard screen will appear. At the bottom of the screen a **"Blue Menu Bar"** will display a selection of options using the "F#" keys. F1- Patient Data, F2- System Data, F4- Special, F6- Wash, F8- Wash & D/S/P, F10- Main.

STEP 5: Select the desired function. To Wash & Disinfect, Press **F8** (F8 WASH & D/S/P). Check level of Chemical Reservoir - Press **F1** to continue. Add **3 oz**. of detergent to processing chamber as it fills with water.

STEP 6: When PROCESSING CHAMBER is full and circulation pump starts purging liquid through the adapters, watch for air bubbles to pass through the SCOPE ADAPTERS, this will ensure flow through the adapters

STEP 7: If you wish to enter Patient Information: Press **F1**, a menu box will appear. To input information, hold down the **ALT KEY** and press the "**E**" **KEY** simultaneously. A new menu box will appear.

A. Type in "Patient Name". Press **TAB (↔)**.

B. Type in "Patient Code". Press **TAB (↔)**.

C. Type in "Physician Name". Press **TAB (↔)**.

D. Type in "Instrument". Press **TAB (↔)**.

E. Repeat step (D.) if there are two instruments for one patient.

F. Hold down the **ALT KEY** and press the "**O**" **KEY**.

G. Repeat STEP 7 for additional patient and scope number 2.

H. Hold down the **ALT KEY** and press the "**O**" **KEY** to return to standard screen.

STEP 8: Upon completion of cycle, Press **F2** to print results and Press **F3** continue, save/clear and return to standard screen.

STEP 9: Alcohol purge scopes, 25cc one scope, 50cc two scopes. Follow "Alcohol Purging" instructions in the manual.

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COMPUTER OPERATING INSTRUCTIONS
FOR SYSTEM 83 PLUS™ 9 DATABASE (DOUBLE BAY)
FOR SYSTEM 83 PLUS™ 10 DATABASE (TRIPLE BAY)

STEP 1: Entire system is turned "On" by opening front door of unit and engaging On/Off switch on CPU located in lower right hand corner. Allow the computer to perform the "Boot Up" procedure. When the computer is ready, a gray/blue **MASTER MENU** screen will appear.

STEP 2: Hold down the **ALT KEY** and press the "**U**" **KEY** to start the program.

STEP 3: The screen will be divided into two or more bays, highlight the desired bay by using the **ARROW KEYS < >** to scroll between the bays. Press **ENTER**.

STEP 4: A blue list of **"Pre-Processing Guidelines"** will appear. Review the necessary steps for preparing your instrument for reprocessing. Press **ENTER.** The standard screen will appear. At the bottom of the screen a **"Blue Menu Bar"** will display a selection of options using the " F# " keys. F1- Patient Data, F2- System Data, F4- Special, F6- Wash, F8- Wash & D/S/P, F10- Main.

STEP 5: Select the desired function: To Wash & Disinfect, Press **F8** (F8 WASH & D/S/P). Check level of Chemical Reservoir - Press **F1** to continue. Add **3 oz**. of detergent to processing chamber as it fills with water.

STEP 6: When PROCESSING CHAMBER is full and circulation pump starts purging liquid through the adapters, watch for air bubbles to pass through the SCOPE ADAPTERS, this will ensure flow through the adapters

STEP 7: If you wish to enter Patient Information: Press **F1**, a menu box will appear. To input information, hold down the **ALT KEY** and press the "**E**" **KEY** simultaneously. A new menu box will appear.

A. Type in "Patient Name". Press **TAB (↔)**.

B. Type in "Patient Code". Press **TAB (↔)**.

C. Press **ENTER.** Use arrow keys **(·)** to highlight "Doctors Name." Press **ENTER.** Press **TAB (↔)**.

D. Press **ENTER**. Use arrow keys **(·)** to highlight "Instrument." Press **ENTER**. Press **TAB (↔)**.

E. Repeat step (D.) if there are two instruments for one patient.

F. Hold down the **ALT KEY** and press the "**O**" **KEY**.

G. Repeat STEP 7 for additional patient and scope number 2.

H. Hold down the **ALT KEY** and press the "**O**" **KEY** to return to standard screen.

STEP 8: Upon completion of cycle, Press **F2** to print results and Press **F3** continue, save/clear and return to standard screen.

STEP 9: Alcohol purge scopes, 25cc one scope, 50cc two scopes. Follow "Alcohol Purging" instructions in the manual.

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SPECIAL SCREEN INSTRUCTIONS

(Summary Page)

The **"SPECIAL"** screen can be accessed by, pressing **"(F4) SPECIAL"** from the **"STANDARD"** screen. This screen allows the user to access special maintenance functions that are not used on an everyday basis.

(F4) D/S/P Allows the user to bypass the wash phase and perform a chemical, immersion and rinse function only. This process is only to be used for reprocessing a clean scope it is not meant to bypass the wash cycle.

(F5) EMPTY Allows the user to empty the contents of the round processing, chamber down the drain.

(F6) PURGE Allows the user to evacuate the chemical reservoir contents down, the drain.

(F7) RETURN D/S/P Allows the user to return the contents of the round processing, chamber back to the chemical reservoir.

(F5) EMPTY, (F6) PURGE and F7 RETURN D/S/P are all maintenance functions which can be stopped by following on screen instructions**-Press (F1) Stop Maintenance.**

When performing **"SPECIAL"** screen functions the unit is in a manual mode and all safety floats are inactive.

To return back to the **"STANDARD"** screen, press (**F3) STANDARD.**

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PRE-PROCESSING GUIDELINES

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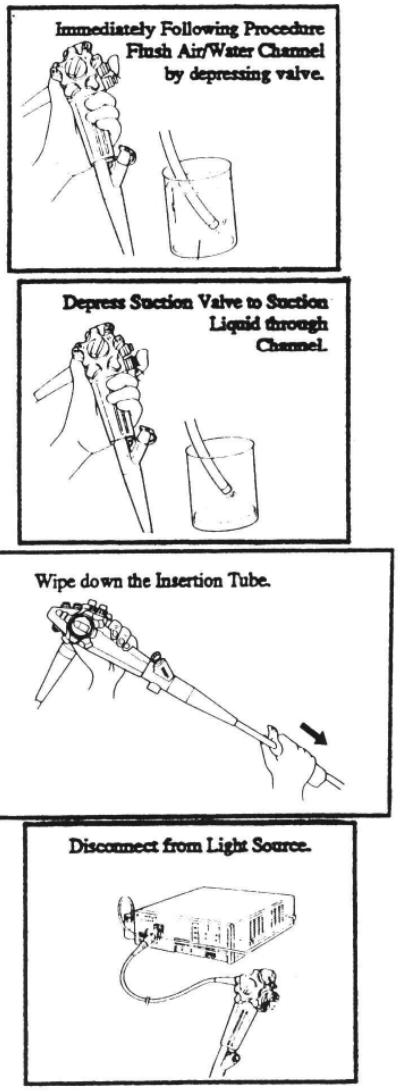
ENDOSCOPE "PRE-PROCESSING" GUIDELINES

Manual "pre-processing" of your endoscope(s) must be completed prior to placing it into the processing chamber of your ***System 83 Plus™ (Washer/Disinfector)***. The following steps have been designed to guide you in the preparation of the endoscope(s) for automatic reprocessing, and specifically, to remove large gross organic contaminants and KY jelly which is immiscible with water; and to assist in preservation of the endoscope(s) by identifying potential damage:

Note: *Specific and unique reprocessing connectors, fittings and channel tubing adapters manufactured and sold by Custom Ultrasonics, Inc. may be required for proper operation of the* ***System 83 Plus™ (Washer/Disinfector)*** *and for thorough reprocess of each different endoscope model.*

With any adapters all parts must be OEM parts or safety issues could arise.



1. Immediately after the endoscopic procedure and before removing the scope from the power source, manually flush a water and detergent solution through the air/water and suction/biopsy channels to remove gross debris.

2. Wipe down the endoscope's insertion tube to remove lubricant and gross contaminants. Take care NOT to exert excess pressure on the jacket, particularly the bending rubber of the distal tip.

3. Remove the scope from the power source, and immediately take the endoscope to the decontamination area. Attach the waterproof cap on video endoscope(s) immediately.

4. Remove the air/water, suction button, biopsy cap(s), and any other removable parts.

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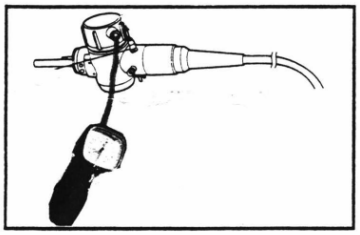
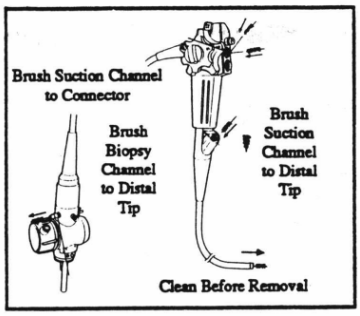


5. *Leak test* to determine the integrity of the endoscope(s) prior to further processing. See step 7 below for cleaning instructions. Refer to the endoscope's operator's manual for the step-by-step procedure for leak testing the endoscope.


Brush Suction Channel to Connector
Brush Biopsy Channel to Distal Tip
Brush Suction Channel to Distal Tip
Clean Before Removal

6. Pass an appropriately sized cleaning brush through the suction/biopsy channel port(s) exiting at both the connector and distal tips, clean the brush, and retract the brush. Continue brushing until there is no debris visible on the brush. (For proper brushing procedure consult your scope manufacturer manual.)

7. Remove all valves (air/water, suction, CO_2, biopsy caps, biopsy selector mechanism, etc.). Consult the scope manual for proper removal and cleaning procedures of valves. Pay special attention to the double biopsy selector mechanism when removing it for manual cleaning. When placing the mechanism back into the scope for reprocessing make certain to set the switch so that both channels are open. The removed valve pieces should be placed in the metal cup and then placed on the bottom tray. The suction button should be placed in the specially designed C clamp holder and then placed on the bottom tray.

8. For machines equipped with automatic lid option, follow these instructions: Raise the automatic lid on the ***System 83™ (Washer/Disinfector)*** by pressing the "up" foot pedal button. Take care when raising the lid to ensure nothing is in its path. Once all the procedures, below, have been completed, close the lid by pressing the "down" foot pedal. Once again make sure nothing is obstructing the moving lid's path and that no adapters or parts of the endoscope(s) remain on the ***System 83™ (Washer/Disinfector)*** Corian™ surface.

9. The following steps are necessary to thoroughly clean and high-level disinfect ERCP scopes. Set the elevator in the half up, half down position. Connect endoscope's elevator cleaning adapter to a 3cc syringe filled with warm water/detergent. Connect the elevator adapter to the endoscope and force detergent/water through the channel several times. If liquid passes through the channel without difficulty, remove syringe, connect elevator cleaning adapter to adapter #16008HP (High Pressure Port) (when using adapters provided by scope manufacturer, check scope adaptation chart to make certain the correct scope manufacturer part # is used) and insert into the ***System 83™ (Washer/Disinfector)*** manifold. Otherwise, continue to repeat steps on page 41. (The Following Instructions are used to unocclude ERCP Elevator Channel).

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10. Place the endoscope(s) in the processing chamber. Select and attach the appropriate endoscope adapters for processing the endoscope(s) in your ***System 83 Plus™ (Washer/Disinfector)***. For instructions on how to hook up the scopes, refer to the **Scope Diagrams, In-Service Program/Report Form and/or the Scope Adaptation For All Model Endoscopes**. The scope adaptation chart can be obtained by visiting our website at www.customultrasonics.com. Contact ***Custom Ultrasonics, Inc.*** if your model endoscope does not appear on any of the above mentioned forms or charts. Or if you are unsure whether you have the proper adapters for each endoscope in inventory.

NOTE: I. When purchasing a new endoscope(s) that are not listed on the original In-Service Program/Report Form 8.32, the facility must contact ***Custom Ultrasonics, Inc.*** immediately. **The part numbers will be supplied for the purchase of the adapters, which are required to process the scope from *Custom Ultrasonics, Inc.***

II. Contact Custom Ultrasonics if you are planning to update your endoscope(s) model or change manufacturers, so that a new set of adapters can be purchased for the use of that scope(s), in the ***System 83 Plus™ (Washer/Disinfector)***.

III. "Re-In-Servicing" of the operating staff, maintenance/bio-med staff and preventative maintenance is available from Custom Ultrasonics, Inc. contact our In- service department for a quote at 215-364-1477.

11. Connect the endoscope adapters to the ***System 83 Plus™ (Washer/Disinfector)*** manifold, starting from right to left. Color order of the adapters does not matter, as long as attaching from the right to the left as stated above. **High pressure ports located below the low pressure adapter manifold, the bulkhead port to the right should be used first when hooking up specialty channels**. The high pressure ports are only used when processing specialty scopes in the chamber (see step 12 for details). The upper or low pressure manifold bulkhead snap-in connectors should only have adapters which are attached to the scope. Any additional loose adapters must be removed from the manifold, (unless the machine equipped with channel monitoring; see instructions on the next page). **For Olympus and Fujinon scopes being processed with the above mentioned bulkhead fitting, a biopsy clamp must be used.** This clamp will help keep the biopsy cleaning adapter secured to the scope during processing. Any adapters not connected to a scope must be removed from the manifold before starting the process.

12. If the machine is equipped with high pressure ports, any two scopes can be reprocessed simultaneously. (If the machine does not have high pressure ports only "**one"** ERCP/colonoscopes endoscope can be processed). If an ERCP scope has a blocked channel, follow special instruction on page 42 or contact the scope manufacturer for instructions on how to clear the blockage.

13. ***System 83 Plus™ (Washer/Disinfector)*** equipped with channel monitoring has a gray box mounted on the top of the machine, next to the monitor, with LED lights, numbered 1 through 10. Numbers 1 through 8 correlate with the low pressure ports on the manifold in the processing chamber. Number 1 is located on the left side of the low pressure manifold and number 8 is located on the right of the manifold. Numbers 9 and 10 on the (gray) box, correlate with the two "high –pressure" ports, located under the low pressure ports. Number 9 located on the left side of the high pressure manifold and 10 being located on the right side of the manifold. The LED lights are used to indicate

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if an endoscope channel is blocked and does not have sufficient liquid flow passing through it during processing. If the LED light is activated during the cycle due to blockage (the red light turns on), the machine will abort, indicating a "water channel" error. If an error occurs, contact ***Custom Ultrasonics, Inc.*** for troubleshooting.

System 83 Plus™ (Washer/Disinfector) equipped with channel monitoring machines has the same manifold configuration as the standard machine. The top eight bulkheads numbers 1 through 8 are used for low pressure (e.g. water, suction, air biopsy, etc.) and the lower two "high-pressure" bulkheads numbers 9 and 10 are used for "specialty channels" (e.g. ERCP, water jet, jet channel etc.). When connecting the endoscope adapters to ***System 83 Plus™ (Washer/Disinfector)*** manifold with channel monitoring start from the right port number 8 to left port number 1. Color order of the adapters does not matter, as long as they start from port number 8 to left port number 1, as stated above. For the "High Pressure" ports below the low pressure manifold, the bulkhead to the right port number 10 should be used first when connecting "specialty channels". The "high pressure" ports are only used when reprocessing "specialty" endoscopes in the chambers. (See step 12 for further details). On the channel monitoring machines all bulkhead snap-in connectors should have tubing attached to bulkheads at all times, when operating an automated cycle. The low pressure adapters cannot be used on the two high pressure lower bulkheads and "vice versa". **When the machine is running, liquid flow through the channels turns off the LED lights on the box located on the machines backplane**. If a blockage occurs, the light will turn "on" and the process will abort. If an error occurs, contact ***Custom Ultrasonics, Inc.*** immediately for trouble shooting help.

When processing ERCP endoscope(s) in a ***System 83 Plus™ (Washer/Disinfector)*** equipped with channel monitoring, make certain to attach the ERCP channel's adapter to the high pressure port(s) starting with port number 10 right to left. Locate the button on the front door marked **High Pressure Channel Monitoring Override Switch** and flip it into the "up" position. The LED light above the switch will blink when engaged. This will override the channel switches to the high pressure bulkheads and allow you to process the ERCP channel without an error occurring. This switch must be used when processing an ERCP scope since the ERCP channel only allows minimal flow and the flow rate is insufficient to activate the channel monitoring switch. Make certain to turn off **the High Pressure Channel Monitoring Override Switch** after processing the ERCP endoscope(s). Do not activate the **High Pressure Channel Monitoring Override Switch** unless processing ERCP scopes.

When injecting 70% isopropyl alcohol into the endoscope's channels at the end of a cycle on a channel monitoring machine make certain to remove any unused endoscope channel adapters from the manifold(s) before injecting the alcohol. Make certain the processing chamber lid is closed.

14. When removing processed scopes from the chamber, make certain to re-check all the channel adapter connections. If any of the adapters have become loose or unattached, reattach all the adapters and reprocess the endoscopes **again** before reuse. Make certain to run an entire Wash/Disinfect cycle. Confirm during cycle there is flow thru channel.

15. Visually confirm there is no significant liquid flowing out of the endoscope's internal channels at its distal tip or umbilicus when removing a scope after processing is complete. Call ***Custom Ultrasonics, Inc.*** Service Department if excess liquid is observed flowing out of the endoscope's internal channels.

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Adapters that have a small white one inch, round disc filter, these filters must be replaced every 6 to 8 weeks or sooner depending on workload. OEM PARTS MUST BE USED. (Part # 16030)

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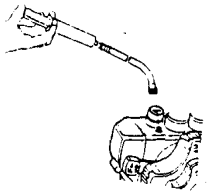
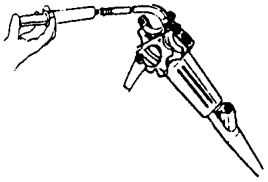
INSTRUCTIONS TO UNOCCLUDE ERCP ELEVATOR CHANNEL

(1)



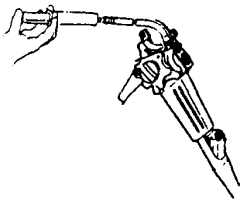
Attach elevator channel adapter

(2)



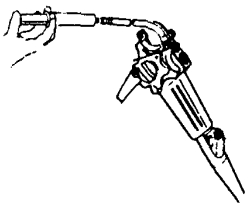
Fill 3cc syringe with warm water and detergent Press plunger

(3)



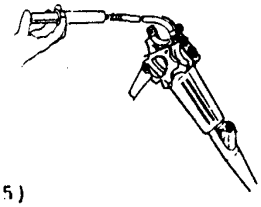
Fill syringe with air and flush

(4)



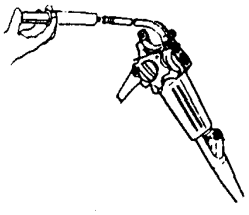
Fill syringe with water and flush

(5)



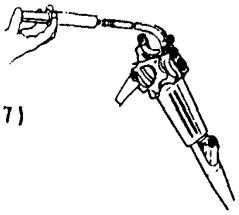
Fill syringe with air and flush

(6)

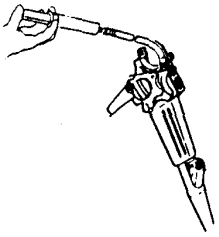


Fill syringe with disinfectant and fill channel. Allow to remain for 20 minutes

(7)

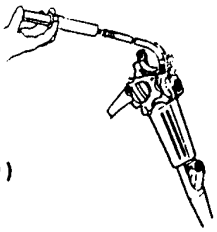


Fill syringe with air and flush



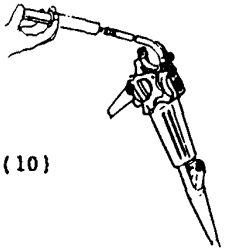
Fill syringe with water and flush

(9)

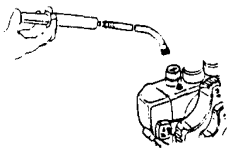


Fill syringe with 70% alcohol and flush

(10)



Fill syringe with air and flush



Remove adapter

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ENDOSCOPE ATTACHMENT INFORMATION

VISIT WWW.CUSTOMULTRASONICS.COM OR CALL 215-364-1477 FOR UP-TO-DATE SCOPE ADAPTATIONS

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ALCOHOL PURGE PRIOR TO REMOVING THE FLEXIBLE ENDOSCOPE FROM SYSTEM 83 PLUS™ (WASHER/DISINFECTOR)

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ALCOHOL PURGE FOLLOWED BY FORCED AIR DRYING

CONFIRM FLOW THROUGH EACH ENDOSCOPE CHANNEL DURING THE MANUAL ALCOHOL PURGE PHASE. VISUALLY INSPECT EACH CHANNEL ADAPTER TO ENSURE THE FLOW OF LIQUID USING AIR BUBBLES AS INDICATORS OF FLOW. BE SURE THE ADAPTERS ARE FIRMILY CONNECTED TO EACH OF THE ENDOSCOPE'S CHANNELS.

CALL *CUSTOM ULTRASONICS, INC* SERVICE DEPARTMENT IF VISUAL CONFIRMATION OF THE FLOW THROUGH EACH ENDOSCOPE CHANNEL CANNOT BE MADE. THE ENDOSCOPE MUST BE REPROCESSED IN A FULL WASH/DISINFECT PROCESS WITH CONFIRMED FLOW THROUGH EACH ADAPTER BEFORE IT CAN BE USED.

Prior to removing the endoscope(s) from the processing chamber, in preparation for endoscope(s) storage, fill a 60cc syringe attached to the gray alcohol adapter with 10cc of air and 25cc of 70% isopropyl alcohol for one (1) endoscope or 50cc of 70% isopropyl alcohol for 2 endoscopes. Make certain not to depress the syringe until instructed to below:

a. Make certain the processing chamber lid is closed and **insert the syringe** adapter into the gray alcohol injection port located on top of the machine.

b. While holding the syringe firmly turn "ON" the Air switch, (a light will indicate the air pump is operating) then inject the alcohol. Remove the syringe adapter immediately after all alcohol is injected.

c. Allow the air pump to run a minimum of sixty seconds to assist in partially drying the channels before removing the "endoscope(s)" from the processing chamber. Note: Visualize liquid (alcohol) is moving through channel adapters followed by air. If adapter tubing is not clearing, the channel may be blocked. Remove the endoscopes, check all channels and notify Custom Ultrasonics, Inc.

d. Turn the AIR switch "OFF". The light will go off indicating the air pump has stopped.

e. When alcohol purging an ERCP scope, attach a 3cc syringe full of air to the ERCP cleaning adapter and inject it into the ERCP channel. Next attach a 3cc syringe full of 70% isopropyl alcohol to the ERCP cleaning adapter and inject it into the ERCP channel. Follow that by injecting a 3cc syringe full of air into the ERCP cleaning adapter attached to the ERCP channel, repeat this step two more times.

f. Remove the endoscope(s) from the processing chamber.

g. Wipe down the endoscope(s) with a soft cloth (lint free), and use additional air to further assist in drying the channels, if desired.

h. The endoscope(s) is ready for reuse or place the endoscope(s) in an appropriate storage area.

i. If **liquid is noticed running out of either end of the endoscope**, one or more of the adapters was not hooked up properly. The scope must be processed through another complete wash/disinfect cycle, followed by alcohol rinse forced air, in order to confirm proper cleaning, chemical immersion and water rinsing. Contact *Custom Ultrasonics, Inc.* for further assistance and advice for checking each adapter. (215-364-1477)

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ALCOHOL PURGE FOLLOWED BY FORCED AIR DRYING

(Machines not equipped with alcohol injection port refer to the following).

CONFIRM FLOW THROUGH EACH ENDOSCOPE CHANNEL DURING THE MANUAL ALCOHOL PURGE PHASE. VISUALLY INSPECT EACH CHANNEL ADAPTER TO ENSURE THE FLOW OF LIQUID USING AIR BUBBLES AS INDICATORS OF FLOW. BE SURE THE ADAPTERS ARE FIRMILY CONNECTED TO EACH OF THE ENDOSCOPE'S CHANNELS.

CALL *CUSTOM ULTRASONICS, INC* SERVICE DEPARTMENT IF VISUAL CONFIRMATION OF THE FLOW THROUGH EACH ENDOSCOPE CHANNEL CANNOT BE MADE. THE ENDOSCOPE MUST BE REPROCESSED IN A FULL WASH/DISINFECT PROCESS WITH CONFIRMED FLOW THROUGH EACH ADAPTER BEFORE IT CAN BE USED.

Prior to removing the endoscope(s) from the processing chamber, in preparation for endoscope(s) storage, fill a 60cc syringe attached to the white alcohol adapter with 10cc of air and 25cc of 70% isopropyl alcohol for one (1) endoscope or 50cc of 70% isopropyl alcohol for 2 endoscopes. Make certain not to depress the syringe until instructed to below:

a. **Insert the syringe** adapter into the bulkhead closest to the left and inject the alcohol. *If the 83 PLUS™ manifold is outside the chamber, insert the syringe adapter into the bulkhead closest to you and inject the alcohol*

b. **Remove the syringe** adapter from the manifold and make sure the processing chamber lid is closed.

c. Turn **"ON"** the **AIR** switch. A light will indicate the air pump is operating.

d. Allow the air pump to **run a minimum of (sixty) seconds** to assist in drying the channels before removing the "endoscope(s)" from the processing chamber. **Note:** Visualize liquid (alcohol) is moving through channel adapters followed by air. If adapter tubing is not clearing, the channel may be blocked. Remove the endoscope, check all channels, and notify Custom Ultrasonics, Inc.

e. Turn the **AIR** switch **"OFF".** The light will go off indicating the air pump has stopped.

f. When alcohol purging an **ERCP** scope, attach a 3cc syringe full of air to the **ERCP** cleaning adapter and inject it into the **ERCP** channel. Next attach a 3cc syringe full of 70% isopropyl alcohol to the **ERCP** cleaning adapter and inject it into the **ERCP** channel. Follow that by injecting a 3cc syringe full of air into the **ERCP** cleaning adapter attached to the **ERCP** channel, repeat this step two more times.

g. Remove the "endoscope(s)" from the processing chamber.

h. Wipe down the endoscope(s) with a soft cloth (lint free), and use additional air to further assist in drying the channels, if desired.

i. The endoscope(s) is ready for reuse or place the endoscope(s) in an appropriate storage area.

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j. If **liquid is noticed running out of either end of the endoscope**, one or more of the adapters was not hooked up properly. The scope must be processed through another complete wash/disinfect cycle, followed by alcohol rinse forced air, in order to confirm proper cleaning, chemical immersion and water rinsing. Contact Custom Ultrasonics for further assistance and advice for checking each adapter. (215-364-1477)

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MAINTENANCE/ROUTINE CHECKLIST

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MAINTENANCE CHECKLIST

1. **Inspect and replace all in-line disk filters on all endoscope channel adapters to scopes. THESE MUST BE REPLACED EVERY 6-8 WEEKS (Part # 16030). NOTE: Be sure to only use filters provided by *Custom Ultrasonics, Inc*.**

2. Lubricate the "o"ring on all channel adapters, alcohol adapter syringe, female bulkheads and the o-ring inside of Custom Ultrasonics, Inc. leak tester end (if applicable) every two weeks.

3. All new valve covers (since approx. June 2000) do not have the sponge material affixed to the lids. The new style rubber pads are not replaced. With this type, periodically inspect the silicone rubber material for wear and tear and report any unusual findings

4. Maintain the cleanliness of the machine. Refer to Good Housekeeping Methods in the manual for assistance.

5. The ***Custom Ultrasonics, Inc.*** water filters attached to the wall behind the machine should be changed every three to six months under normal conditions. If a pressure differential of 20 to 25 psi exists between inlet and outlet sides of the .1 micron filter gauges, the .1 micron bacterial filter(s) (**Part # 13017)** should be changed by the biomedical or maintenance department. This change is approximately at 6 mo. intervals during normal operation of the system. The 25 micron (**Part # 13015**) and/or 5 micron (**Part #13016)** pre-sediment filter(s) should be changed every three months or when dark in color. **Often, processing fill times increase significantly indicating the need to change the filter.**

6. Refer to Disinfecting Detergent Line procedure form when replacing detergent bottle(s).

QUARTERLY MAINTENANCE

(3 months)

1. Have biomedical or maintenance perform routine maintenance procedure from the biomedical manual (as instructed during the initial installation of the machine).

2. Change any and all 93-1000 vapor recovery system filters. [**(Back Pack Filter-Part # 21017) (Floor Vacuum Filter Pack-Part # 21003)]** Refer to re-ordering section of manual.

3. Refer to step 5 above for replacing Custom Ultrasonic water filters. **Inspect and replace all in-line disk filters on all adapters to scopes. THESE MUST BE REPLACED EVERY 6-8 WEEKS (Part # 16030). NOTE: Be sure to only use filters provided by Custom Ultrasonics.**

4. Change HEPA filter element cartridge on output side of machine air pump (Part **# 13075).**

5. Replace 100 micron capsule filter only on Channel Monitoring (flow switch) system (**Part#11087).**

6. Refer to Disinfecting Alcohol Line procedure every 3 months.

7. Refer to Disinfecting Detergent Line procedure form when performing preventive maintenance.

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SEMI-ANNUAL MAINTENANCE

(6 months)

1. Sterilize water filter canisters and water inlet lines when changing cleared .1 micron bacterial filter. Refer to form: Installation, Disinfection & Replacement Procedures For The Water Filter Assembly.

ANNUAL MAINTENANCE

(12 months)

1. Change black, screw on air filter on input side of machine air pump (**Part # 20010)**

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OPERATOR'S ROUTINE CHECKLIST

- ☐ Inspect and replace all in-line, disk filters for all purging adapters to the endoscopes. **THEY MUST BE REPLACED EVERY 6-8 WEEKS (Part # 16030).** (Use only those filters sold by Custom Ultrasonics, Inc.).
- ☐ Silicone the female o-rings for all channel adapters every two weeks.
- ☐ Check the silicon rubber on the valve covers for wear replace if required every two weeks.
- ☐ **Daily** Housekeeping practices will extend the life of the system.
- ☐ Check the water filters gauges on the wall **daily.** If there is a pressure differential of 20 to 25psi between the inlet and outlet sides of any of the filters, then it must be replaced.
- ☐ Request Maintenance personnel to perform **routine maintenance** every 90 days.
- ☐ **Leak test** your instruments routinely before cleaning in accordance with the endoscope's operator's manual.
- ☐ Check each endoscope adapter at the end of each cycle, to confirm that none have become loose or disconnected. If so, reprocess the endoscope again using a complete wash-disinfect cycle.
- ☐ Routinely monitor the concentration of the germicide to ensure it is above its minimum effective concentration.

CLEANING THE METAL FILTER SCREEN:

- ☐ Located in the processing chamber, there is a side compartment covered by a perforated stainless steel cover. On removing the cover, a housing containing a filter screen will be found.
- ☐ Unscrew the housing and remove and thoroughly clean the filter screen.
- ☐ Replace the screen making certain it is seated properly within the housing frame.
- ☐ Make certain the housing and screen are secure before hanging the perforated stainless steel cover.

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CUSTOM ULTRASONICS
DO'S AND DON'TS

1. Always refer to **Scope Diagrams, In-Service Program/Report Form, and Scope Adaptation For All Model Endoscopes** with questions on hooking up scopes. The scope hook-up information can also be found at www.customultrasonics.com.

2. Plug adapters into the bulkheads manifold starting from the far right moving to the left. (Do not skip any adapter ports). If **CHANNEL MONITORING** is featured, every bulkhead must have adapters. The lower high pressure ports have their own special adapters. These high-pressure port adapters must be correct or machine will error with a **WATER CHANNEL ERROR.**

3. For a machine without Channel Monitoring option, only use adapters which are connected to a scope. Disconnect the unused second set of adapters from the bulkhead manifold if only reprocessing one scope.

4. Make certain to replace all filters with ***Custom Ultrasonics, Inc.*** OEM parts, involved with the operation of the machine. (Example: water filters, disk filters, capsule, etc.)

5. Only **OEM** (Original Equipment Manufacturer) adapters and accessories provided by Custom Ultrasonics, Inc. or used by CU during validation (simulated "in-use") testing, e.g., (Olympus, Pentax, etc.) can be used in the System 83 Plus. All endoscope drawings and charts have been provided to staff, showing the proper attachments per endoscope and explaining any endoscope manufacturer's adapter parts as needed.

6. Check disinfectant level in reservoirs on a daily basis, add additional disinfectant if necessary. Be alert to any unusual or significant loss of disinfectant. Check the concentration of disinfectant as required by the chemical manufacturer.

7. Do not place water bottles, syringes, sponges, containers, etc. into the processing chamber.

8. Never operate system without at least three adapters plugged into the manifold. **Failure to do this can cause significant damage to the system.**

9. Do **NOT** place anything on the ***System 83 Plus™ (Washer/Disinfector)*** lids. Doing so will damage the lids. Be certain that nothing can obstruct the lid from closing (Example: Scopes, adapters, clamps, etc.) **NOTE: Take extra precaution for power lids.**

10. **Do not place anything to be disinfected in the chemical reservoir.**

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DISINFECTANT TRANSFER SYSTEM

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DISINFECTANT TRANSFER CAP INSTRUCTIONS FOR *SYSTEM 83 PLUS*™ *(WASHER/DISINFECTOR)* WITH THE CHEMICAL TRANSFER OPTION

1. Remove all adapters except the (3) adapters on the right side of the manifold.
2. Turn on the air switch to purge any remaining liquid out of the manifold (approximately: 1 minute).
3. Turn off the air pump.
4. Remove CAP(S) from chemical bottle **(DO NOT REMOVE FOIL COVER).**
5. Ensure you have the disinfectant transfer CAP, the air input adapter and the chemical transfer adapter tube.
6. Puncture the foil on the chemical container (Approximately 1" in diameter) and lower the disinfectant transfer CAP'S tube into the container.
7. Be sure CAP is straight and tight **(DO NOT CROSS THREAD).**
8. Attach transfer adapter tube to CAP (fitting located on the top of the CAP) and then attach the other end to the white bulkhead located behind the wash chamber lid.
9. Attach the air input adapter to the CAP (fitting located on the side) to the last bulkhead on the right side of the manifold.
10. Be sure all connections are secure.
11. Turn on air switch.
12. Liquid will flow through tube and into the reservoir.
13. Tilt the bottle to ensure all chemical has exited the bottle.
14. Turn off air pump, allow 5 seconds for air to exit the bottle and disconnect the (2) adapters from the CAP.
15. Repeat (except step 1, 2 and 3) (5) more times (once for each bottle) for 16 ½" Chamber System or (7) more times (once for each bottle) for 19" chamber system (per bay).
16. Once completed place CAP(S) and disinfectant transfer tube adapter in the wash chamber and run a cycle.
17. Dry CAP(S) and transfer adapter tube and store.

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"F6" Safety Key Cover Guidelines

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Installation Instructions for the F6 Hinged, Self-closing Safety Key Cover Cherry Keyboard

1. Verify that the manufacturer of the keyboard you are currently using is a Cherry Keyboard

2. Verify that the part number on the enclosed F6 Hinged, Self-closing Safety Key Cover matches the part number for the F6 Hinged, Self-closing Safety Key Cover for the Cherry keyboard that you are currently using. **The part number for the F6 Hinged, Self-closing Safety Key Cover for the Cherry keyboard is 26042**
3. Without removing the protective plastic membrane on your keyboard (**verify that all of the keys are clearly visible through the plastic membrane and that the membrane is not discolored*),** slide the F6 Hinged, Self-closing Safety Key Cover over the **F6 key**, which is located on the top row set of function keys on your keyboard. (See illustration).

4. Verify that the F6 Hinged, Self-closing Safety Key Cover is placed properly over the **F6 key** on your keyboard. (see illustration)
5. Please refer to the Custom Ultrasonics Operator's Manual regarding the "Good Housekeeping" procedures for cleaning the keyboard protective membrane.

* Contact Custom Ultrasonics to purchase a new protective plastic membrane if your plastic keyboard membrane is discolored. Part number 26004 and specify the type of keyboard you are using.

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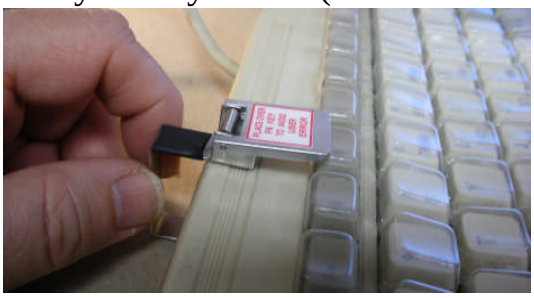
Installation Instructions for the F6 Hinged, Self-closing Safety Key Cover SIIG Keyboard

1. Verify that the manufacturer of the keyboard you are currently using is a SIIG keyboard

SIIG
FCC ID: FKD46AK110P
MODEL No.: KB1903 (AT)
KB1948 (PS/2)
This device complies with part 15 of the FCC rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) This device must accept any interference that may cause undesired operation.
MADE IN CHINA
S/N J33M19000348 JK-A10032-B

2. Verify that the part number on the enclosed F6 Hinged, Self-closing Safety Key Cover matches the part number for the F6 Hinged, Self-closing Safety Key Cover for the SIIG keyboard that you are currently using. **The part number for the SIIG keyboard is 26043**
3. Without removing the protective plastic membrane on your keyboard (**verify that all of the keys are clearly visible through the plastic membrane and that the plastic membrane is not discolored*),** slide the F6 Hinged, Self-closing Safety Key Cover over the **F6 key**, which is located on the top row set of function keys on your keyboard. (see illustration).



4. Verify that the F6 Hinged, Self-closing Safety Key Cover is placed properly over the **F6 key** on your keyboard. (see illustration).
5. Please refer to the Custom Ultrasonics Operator's Manual regarding the "Good Housekeeping" procedures for cleaning the keyboard protective membrane.

*Contact Custom Ultrasonics to purchase a new protective plastic membrane if your plastic keyboard membrane is discolored. Part number 26004 and specify the type of keyboard you are using.

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F6 Hinged, Self-closing Safety Key Cover Instructions for Utilizing the F6 Key on the Cherry Model Keyboard

1. On the **Standard Screen** of the System 83 Plus Washer/Disinfector, the F6 Wash key can be utilized by lifting up the F6 Hinged, Self-closing Safety Key Cover (see Illustration 1) and pressing down on the F6 key (see Illustration 2). This is done with the intention of performing a WASH only cycle. Note: This will not properly disinfect the endoscope(s) as this is a wash only cycle. A WASH D/S/P (F8) must be selected to properly wash and disinfect a scope.

2. On the **Special Screen** of the System 83 Plus Washer/Disinfector the F6 Purge key can be utilized by lifting up the F6 Hinged, Self-closing Safety Key Cover (see Illustration 1) and pressing down on the F6 key(see Illustration 2).

Cherry Model Keyboard (Illustration 1)

Cherry Model Keyboard (Illustration 2)

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F6 Hinged, Self-closing Safety Key Cover Instructions for Utilizing the F6 Key on the SIIG Model Keyboard

1. On the **Standard Screen** of the System 83 Plus Washer/Disinfector, the F6 Wash key can be utilized by lifting up the F6 Hinged, Self-closing Safety Key Cover (see Illustration 1) and pressing down on the F6 key (see Illustration 2). This is done with the intention of performing a WASH only cycle. Note: This will not properly disinfect the endoscope(s) as this is a wash only cycle. A WASH D/S/P (F8) must be selected to properly wash and disinfect a scope.

2. On the **Special Screen** of the System 83 Plus Washer/Disinfector the F6 Purge key can be utilized by lifting up the F6 Hinged, Self-closing Safety Key Cover (see Illustration 1) and pressing down on the F6 key (see Illustration 2).

SIIG Model Keyboard (Illustration 1)

SIIG Model Keyboard (Illustration 2)

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Troubleshooting Guide

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Problem Solving

SYSTEM DIAGNOSTICS:

The **SYSTEM DIAGNOSTICS PROGRAM** should be performed by trained Biomedical and/or Maintenance personnel during maintenance, service or in response to a system **FAULT**. To check the operation of the mechanical components in your ***System 83 Plus™ (Washer/Disinfector)***, return to:

MAIN MENU BAR

RUN CU--MASTER DATA—REPORTS—MISC--DAY/MO/TIME/YEAR

- Press the (**ALT) and (C) keys** simultaneously and press (**ENTER)**.
- Using the arrow keys, highlight **SERVICE** and Press **(ENTER)**.
- Using the arrow key, move to the **"digital I/O test"** and Press, **(ENTER).**
- Select the BAY with the arrow key and a light will illuminate.
- Arrow down to the component in question and press the **SPACE BAR.**
- The component red light will appear and the component engaged. **If the light does not appear, the computer I/O Board should be checked. If the component functioned, press the SPACE BAR to turn off the component. If the component light appears but the component does not, check AC circuit line.**
- To exit **SYSTEM DIAGNOSTICS** Press (**ENTER).**
- To return to the main program, move cursor to **EXIT** and press (**ENTER).**

SYSTEM FAULT:

If the operating fault occurs during the process, the computer will abort the process, a **BEEP** will be heard and "(**F1) with the cause for the fault**" will appear on the monitor. The **RED** arrow on the process dial will move to **COMPLETE. Make certain to note the fault on a pad before clearing the fault before pressing F1 to clear the fault**.

FAULT CODES:

1. **CHECK WATER CHANNEL -** No liquid entering the endoscope channels. Contact BIOMEDICAL.

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2. **SAFETY FLOAT ACTIVATED -** Indicates the safety float has been elevated either in the reservoir or the processing chamber turning the system off. Press the (**F4)** key **Special Programs**.

   a. If water is in the processing chamber causing the float to elevate, press **(F5)** to empty the processing chamber and when empty press **(F1).**

   b. If disinfectant is in the processing chamber causing the float to elevate, press **(F7) Return DSP** to return the disinfectant to the reservoir. When complete press **(F1).**

NOTE: CHECK ALL THE FLOATS TO MAKE CERTAIN THEIR MOVEMENT IS NOT RESTRICTED ON THEIR SHAFTS.

3. **INVALID START STATE -** Error will occur if the operator attempts to start a cycle without clearing the cause for a fault shutting the system down.

4. **DISINFECTANT IMMERSION TIME STALLED WILL NOT ADVANCE -** The level of disinfectant in the reservoir is insufficient.

SOLUTION: SLOWLY ADD DISINFECTANT TO THE PROCESSING CHAMBER UNTIL **THE LIGHTS ON THE MONITOR FOR THE FLOAT AND PURGE PUMPS COME ON.** POUR THE BALANCE OF THE DISINFECTANT INTO THE RESERVOIR WHEN THE DISINFECTANT IS RETURNED TO THE RESERVOIR. CHECK THE LEVEL OF THE DISINFECTANT IN THE RESERVOIR.

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RE-ORDERING SECTION AND PART LIST

PARTS, PRICING AND ORDERING INFORMATION ARE LOCATED ON-LINE @
WWW.CUSTOMULTRASONICS.COM

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CUSTOM ULTRASONICS INC.

Hours of operation- 8:00am to 5:00pm eastern time
Office number (215) 364-1477
Fax number (215) 364-7674
Fax parts orders (215) 364-8760
www.customultrasonics.com

Notify us if you receive a new scope, new detergent, or new chemical. If you have a question about our hookups or operation of our machine please don't hesitate to call or email us at info@customultrasonics.com

Mailing address: 144 Railroad Dr
Ivyland, Pa 18974

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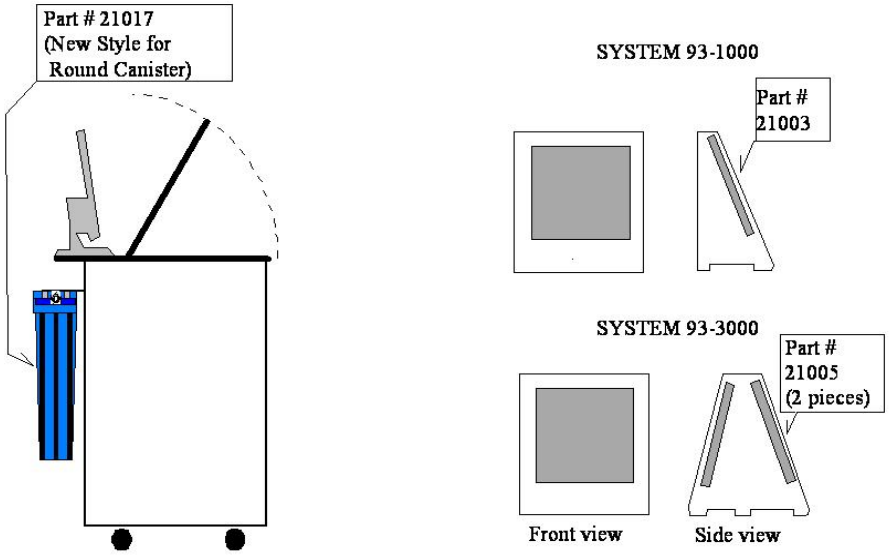
CUSTOM ULTRASONICS INC.

Decontamination Systems for the Health Care Industry

SYSTEM 93-1000 or 93-3000

GLUTARALDEHYDE VAPOR RECOVERY SYSTEM

RE-ORDERING REPLACEMENT FILTER PACKS



NUMBER	DESCRIPTION
21017	FILTER MEDIA CARTRIDGE FOR ROUND 20" CANISTER FILTER
21003	FILTER MEDIA CARTRIDGE FOR 93-1000 FLOOR VAC
21005	FILTER MEDIA CARTRIDGE FOR 93-3000 FLOOR VAC

21001 FILTER MEDIA PACK FOR #21000 FRAME (OLD STYLE) NO LONGER AVAILABLE
CONTACT CUSTOMER SERVICE FOR REPLACEMENT INFORMATION

P.O. Box 850 Buckingham, PA 18912
Phone 215-364-1477 FAX 215-364-7674
www.customultrasonics.com

PRICING IS SUBJECT TO CHANGE.

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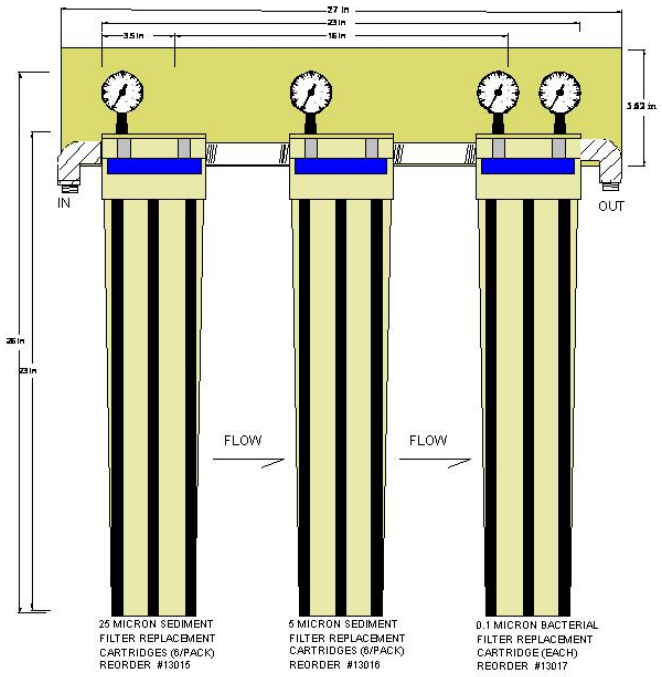
CUSTOM ULTRASONICS INC.

Decontamination Systems for the Health Care Industry

RE-ORDER REPLACEMENT WATER FILTERS



Part #	Description
13015	Water Sediment Replacement Filters, 25 micron
	Six (6) filter cartridges per case, one case minimum
13016	Water Sediment Replacement Filters, 5 micron
	Six (6) filter cartridges per case, one case minimum
13017	Water Bacteria Replacement Filters, 0.1 micron
	One (1) filter cartridge per case, one case minimum

NOTE: 5 and 25 micron filters should be changed at least every 90 days
0.1 micron bacteria filters should be changed at least every 180 days
or on water pressure differential of >20—25 PSI
Filter replacement frequency is dependent on water quality and volume used.

Pricing is subject to Change

Custom Ultrasonics Inc.

Re-ordering Tergal Detergent

Thorough cleaning …
It's the key to success
To Remove contaminates and ensure patient care, instruments and medical devices must be thoroughly cleaned before disinfection or sterilization. All too often, improper cleaning agents yield incomplete results.

Tergal 800...is uniquely formulated and Ideally suited for removing proteinaceous soil in automated endoscope and surgical instrument reprocessors.

Tergal 800…the mildly alkaline penetrating agents remove blood and other organic material quickly and completely, rinse freely without leaving a residue, and especially effective in removing contaminates in hard-to-reach areas such as lumens and box locks.

Let us know what you are cleaning...we'll show you how **Tergal 800** can do the job for you...quickly, safely, and economically.

NUMBER	DESCRIPTION
13013	Detergent Pump (Gallon Bottle)
13020	Tergal 800 Detergent Four (4) Gallons per case Two (2) case minimum

Please Have Purchase Order Ready and fax Directly to Custom Ultrasonics Fax: 215-364-8760

Pricing is subject to change

MATERIAL SAFETY DATA SHEET
OSHA-20 DATA

SECTION I

MANUFACTURER: CUSTOM ULTRASONICS TELEPHONE: 215/364-1477 ADDRESS: 144 Railroad Drive, Ivyland, PA 18947

CHEMICAL NAME: Detergent, free rinsing NAME: TERGAL 800 CHEMICAL FAMILY: Cleaner and degreaser FORMULA: NA

SECTION II - HAZARDOUS INGREDIENTS

HAZARDOUS INGREDIENTS	PERCENT	TLV UNITS
Dipropylene glycol methyl ether CAS 34590-94-8	<5%	100

SECTION III - PHYSICAL DATA

BOILING POINT: 212°F SPECIFIC GRAVITY: 1.075 VAPOR PRESSURE: 22 MM PERCENT VOLATILE: >78

VAPOR DENSITY: NA EVAPORATION (WATER = 1): 1 SOLUBILITY IN WATER: 100% pH: (undiluted) 10-12

APPEARANCE/ODOR: Clear blue liquid, pleasant mild detergent odor. OTHER:

SECTION IV - FIRE AND EXPLOSION HAZARD DATA

FLASH POINT/METHOD: NONE, TCC FLAMMABLE LIMITS: NA EXTINGUISHING MEDIA: NONE REQUIRED

SPECIAL FIRE FIGHTING PROCEDURES: NONE REQUIRED

SECTION V - HEALTH HAZARD DATA

THRESHOLD LIMIT VALUE: OSHA & ACGIH TWA/TLV of 100 on >5% of concentrate

EFFECTS OF OVEREXPOSURE: None from the vapors. Eye irritation from contact with the cleaner concentrate. Skin irritation from prolonged contact with the concentrate. Diarrhea from ingestion.

EMERGENCY FIRST AID PROCEDURES: Wash from eyes with water until irritation stops. If irritation persists see a physician. Remove contaminated clothing and wash before reuse. If ingested drink lots of water and see a physician. Note to physician - Treat as soap or detergent concentrate ingestion. Wash concentrate from skin with water.

SECTION VI - REACTIVITY DATA

STABILITY: Unstable- Stable - X Conditions to avoid –

INCOMPATIBLE MATERIALS: NONE HAZARDOUS DECOMPOSITION PRODUCTS: NONE

HAZARDOUS POLYMERIZATION: May occur - Will not occur: X Conditions to avoid:

SECTION VII- SPILL OR LEAK PROCEDURES

STEPS TO BE TAKEN IF SPILLED OR RELEASED: Pick up excess with mop or wet-vac and wash residue to sewer. Nontoxic and biodegradable.

WASTE DISPOSAL METHOD: Sewer, landfill or incinerate following local laws.

SECTION VIII - SPECIAL PROTECTION INFORMATION

RESPIRATORY PROTECTION: Not required when used as directed.

VENTILATION: No Local exhaust- Mechanical . Special . Other

GLOVES: Not required EYE PROTECTION: Yes, goggles or glasses.

OTHER PROTECTIVE EQUIPMENT: Water source for eye wash out and skin wash.

SECTION IX - SPECIAL PRECAUTIONS

HANDLING AND STORAGE: Store between 35 °F and 100 °F in closed containers. Keep out of reach of children.

OTHER PRECAUTIONS: Wash hands after handling concentrate.

Form MSDS 8103
[Rev. NOV 7, 2006]

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Service Section

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SERVICE PROGRAM INSTRUCTIONS FOR CUSTOM ULTRASONICS PLUS "DOS" PROGRAM

STEP 1: Entire system is turned "On" by opening front door of unit and engaging On/Off switch on CPU located in lower right hand corner. Allow the computer to perform the "Boot Up" procedure. When the computer is ready, a gray MASTER MENU screen will appear.

STEP 2: Red highlighted letters on menu are the activation keys. Hold down the ALT key and press the C key.

STEP 3: Press the down arrow key and highlight SERVICE, press Enter.

STEP 4: A blue selection bar will appear on the bottom.

STEP 5: Use arrow key and highlight DIGITAL I/O. Press Enter. A component screen will appear (see below) the highlighted cursor will be located on 1-1. This cursor is controlled by the arrow keys.

		Bay Outputs 1 2 3 4	Bay Inputs 1 2 3 4	
Ultrasonics	1	O O O O	O O O O	1 flow
Drain pump	2	O O O O	O O O O	2 float
Drain sol.	3	O O O O	O O O O	3 safety
Water in sol.	4	O O O O	O O O O	4 lubrication
Circulation pump	5	O O O O	O O O O	5 water channel
Disinfectant pump & sol.	6	O O O O		
Disinfectant feed sol	7	O O O O		
Disinfectant return sol.	8	O O O O		
Residual drain pump & sol.	9	O O O O		
Air pump & sol.	10	O O O O		
Pump lubricant (81); detergent (83)	11	O O O O		
Reservoir heating pad	12	O O O O		
Bay heating pad	13	O O O O		
Detergent pump (81)	14	O O O O		
Enzyme pump (81)	15	O O O O		

STEP 6: To activate the component, highlight the circle and press the SPACE BAR. To de-activate the component press the SPACE BAR again. Multiple components can be turned on at the same time.

STEP 7: Only outputs can be activated by the cursor and space bar. To end service program, press Enter. The blue bar will appear. Use arrow keys and highlight EXIT. Press Enter.

STEP 8: From the gray Master Menu screen, return to standard operation screen by holding down the Alt key and pressing the U key.

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ROUTINE MAINTENANCE PROCEDURE

To maintain ***System 83 Plus™ (Washer/Disinfector)*** in optimal condition, routine maintenance procedures must be performed on a quarterly basis by a qualified Biomedical Engineer or trained maintenance personnel.

MAINTENANCE PROCEDURES:

If possible, routine maintenance on ***System 83 Plus™ (Washer/Disinfector)*** should be performed when the disinfectant has expired and can be drained. To drain the system go to the **Standard Menu Bar** and press function key (**F4).**

(F1) PATIENT **(F2)** SYSTEM DATA **(F4)** SPECIAL **(F6)** WASH **(F8)** WASH &D/S/P **(F10)** MAIN

A Special Menu bar appears.

(F1) PATIENT **(F2)** SYSTEM DATA **(F3)** STANDARD **(F4)** D/S/P **(F5)** EMPTY **(F6)** PURGE
(F7) D/S/P RETURN **(F10)** MAIN

On Pressing (**F6),** the disinfectant is transferred from the reservoir to the processing chamber and down the main waste line. When complete, press **(F1)** as noted on the monitor. If water is in the processing chamber, press (**F5)** and when empty press (**F1).**

Before turning the hot and cold water lines OFF on the wall, note the settings of the valves so they can be returned to the same setting on completion of the Maintenance Procedures. **The water temperature should be 110 degrees F and never exceed 120° Fahrenheit**.

Disconnect the AC plug from the wall receptacle and turn Circuit Breaker OFF.

Open the front door of the cabinet, turn the computer OFF and inspect for any leakage of water or disinfectant. After inspecting, move the system away from the wall and remove the screw at the base of the rear panel(s) and inspect for leakage. **The panel is steel, heavy, use caution upon removing the door, do not get your fingers caught between the panel and floor under the doors.**

The incoming water line hoses connected to ***System 83 Plus™ (Washer/Disinfector)*** have filter screens. The hoses should be removed and the screens cleaned or replaced. **Take precautions for the residual water in the hoses**.

The solenoids in ***System 83 Plus™ (Washer/Disinfector)*** include **Water Inlet, Hand Spray, Drain, Residual Drain, Disinfectant Return, Detergent Injection** and an **Air Pump** inside the rear panel and a **Disinfectant Solenoid** inside the front panel.

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Using towels to collect residual water and disinfectant in the plumbing lines, remove the 4 bolts holding the electrical coil housing to the solenoid's base. The solenoid contains **a rubber diaphragm, plunger** with a **small spring** and a **screen.** The parts should be cleaned and inspected for wear.

On re-assembly, check the lower housing of the solenoid for wear and account for the individual parts for each solenoid on assembly. **Take care not to torque the 4 bolts down so hard the diaphragm becomes distorted**. A little over hand tight will produce the proper seal.

The drain and disinfectant feed pumps are **magnetic drive**. There is no need to disassemble the pumps unless there is a problem.

Check all compression fittings, unions, ball valves and tubing to be certain they are secure and the PVC plumbing connections show no leakage.

CAUTION: Check the wiring of the transducers on the bottom of the processing chamber and the **ground lug on the bottom plate** next to the gray shielded cable to the generator. If a broken wire is found, re-attach the wire with silver solder.

Clean the front and rear louvers of the ultrasonic generator. Make certain the white interface box under the shelf is secure and there is no damage to the cables and the (4) plugs are secure.

Carefully replace the rear panel.

Move the ***System 83 Plus™ (Washer/Disinfector)*** back to the wall. **Make certain the water inlet hose(s), drain hose(s) and residual drain hose(s) are secure and not kinked.**

Install the AC plug(s) into the wall receptacle(s).

There are 2 operating floats behind the metal cover in the scope processing chamber.

Make certain they are clean and move up and down on the shaft freely. If the floats must be removed, look for the 2 magnets inside the float and their position on the shaft. Check the floats in the disinfectant reservoir to make certain they move freely.

Beginning at the right side of the female purging manifold, in the processing chamber, lubricate the manifold by placing a drop of silicon on the male end of each flexible endoscope adapter and insert it into the manifold.

Clean the fume recovery system sensors in the processing chamber and disinfectant reservoir.

Engage the Circuit Breaker, turn the Computer ON and follow the instructions on the following page for testing the individual components.

After completing the testing of the components, fill the reservoir with water, make certain the switches on the front door panel are in the down position and press function key **(F8)** for **"WASH & D/S/P".**

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On completion, press (**F4)** SPECIAL, a new **Menu Bar** will appear. Press **(F6)** to purge the system of the water and when empty Press **(F1).**

Fill the processing chamber with ½ gallon of disinfectant and press **(F7).** The disinfectant will transfer from the processing chamber into the reservoir. When the transfer is completed press **(F1).** In turn, press **(F6)** to purge the system and when completed press **(F1)** completing the Routine Maintenance Procedures.

PARTS REPLACEMENT SCHEDULE:

Check with the operators of the system and make sure they are replacing the line filters in the scope adapters (Part # 16030) every six to eight weeks or more often where there is a high workload.

Change the HEPA filter cartridge on the output side of the air pump every three (3) months (Part # 13075).

Every six (6) months, remove the sensor (resembles a spark plug) in the PVC tee before the input of the drain pump(s). Clean and Teflon™ tape the spark plug threads and reassemble. Make certain the low voltage lines to the sensor and ground are secure.

High-level disinfection of its internal components, solenoids and plumbing lines during routine endoscope reprocessing. Periodically scheduled "auto-disinfection/sterilization" of the internal components, solenoids and plumbing lines of the ***System 83 Plus™ (Washer/Disinfector)*** is still required, such as when changing the bacterial filter. Refer to the ***System 83 Plus™ (Washer/Disinfector)*** operator instructions. ***Contact Custom Ultrasonics, Inc.*** for more information. *Failure to perform this procedure as recommended may have adverse consequences.*

MUST BE OEM PARTS ONLY.

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INSTALLATION, DISINFECTION & REPLACEMENT PROCEDURES FOR THE WATER INLET FILTER ASSEMBLY & WATER INLET PLUMBING LINE(S)

REQUIRED PARTS:

(1) fresh gallon of 2% activated germicide per water inlet(s) set
rubber band(s) per chamber (if machine is equipped with rinse hose)
large pliers and/or channel locks
towels, gloves and protective clothing and glasses
germicide hand pump assembly…….…. #11011
25 micron pre-sediment filter(s) (for triple canister set ups)...…… #13015
5 micron sediment filter(s)…….…….……... #13016
0.1 micron bacteria filter(s)...…… #13017
removable filter gauges…….……..…..#13040 & #13042
filter wrench……..…… #13045
hose Y connector…….. #11038

OPTIONS:

replacement water inlet hose(s)……...…..….#11004
replacement O-Ring for each filter canister..…….……...#13038

"WATER SUPPLY" refers to all available hot and cold water lines supplying the equipment from a 0.1 micron bacteria filter(s) preceded by a 5 micron, 25 micron pre-filter or both.

***IMPORTANT: Attach endoscope adapters to all bulkheads on the manifold of the *System 83 Plus™ (Washer/Disinfector)* and confirm adapters are attached to both high pressure ports; otherwise, damage to the purge pump may occur.

THE FOLLOWING PROCEDURES MUST BE PERFORMED:

1. When there is a 20 to 25 PSI PRESSURE DIFFERENTIAL across the inlet (see "E2" on diagram) and outlet (see "E3") gauges of the 0.1 micron bacteria filter(s) (see "J"), while the machine is filling.

2. Under normal operating conditions, replace the 0.1 micron bacteria **once every 6 MONTHS** or more often – refer to step #1..

NOTE: This procedure does not have to be performed when changing the 5 or 25 micron pre-filter(s) (see "G"). The 5 or 25 micron pre-filter must be replaced EVERY 3 MONTHS and/or when the entire processing time increases 5 to 10 minutes.

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STEP #1

STERILIZATION OF FILTER ASSEMBLY PROCEDURE:

1. Turn the hot and cold water valves "OFF" at the wall (see "A" on diagram).

2. Turn the computer "ON" and enter the program. Once in the operating screen press, **Wash** button indicated on the screen. Allow the water to drain out of the plumbing lines and then turn off the computer (**NOTE:** use the correct shut down procedure when needed before turning off power). Remove the machines electrical plug(s) from the wall outlet for safety (see "O").

3. Unscrew the lower section of the 5 micron sediment (see "F2") and 0.1 micron bacteria (see "I2") filter canisters. Remove and dispose of the filters since they cannot be reused (see "G" & "J"). Clean the canisters and O-ring with soap and water and rinse thoroughly.

4. Disconnect the water filter supply hose(s) (see "B") from the input and the machine water inlet hose (see "K") from the output connectors of the filter assembly.

5. Remove all pressure gauges (see "E1, E2 & E3") from the filter upper canister(s) (see "F1 & I1") and the four (4) wing nuts holding the aluminum frame (see "D") to the white wall mount bracket (see "C").

6. Send the cleaned filter canisters, O-rings (see "H") and the aluminum frame, with the new 0.1 micron filter(s) to be heat sterilized **for 30 minutes at 121°C (252°F).**

   NOTE: The plastic outer wrap that the replacement 0.1 micron filter comes in must be removed prior to heat sterilization.

FILTER RE-ASSEMBLY PROCEDURE:

1. Connect the aluminum frame (see "D") to the wall bracket (see "C"), secure it with the four (4) wing nuts and connect all pressure gauges on the filter assembly.

2. Install the 5 micron sediment filter (see "G") by securing the male end firmly up and into the female socket of the upper canister (see "F1") attached to the aluminum frame. Carefully lubricate the O-Ring (see "H") with distilled water, seat it and screw the lower canister (see "F2") into the upper canister until secure.

3. Expose only the male end of the 0.1 micron bacteria filter (see "J") from the sterile packing being careful not to contaminate the filter. Holding the sterile packaging, insert the male end of the filter firmly up and into the female socket of the upper canister (see "I1"). When firmly in place, remove the remaining sterile packaging. Carefully lubricate the O-Ring (see "H") with distilled water, seat it and screw the lower canister (see "I2") into the upper canister (see "I1") until secure.

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STEP#2

DISINFECTION OR STERILIZATION OF WATER INLET LINES PROCEDURE:

1. If you elect to replace the water inlet hose(s), (see "K" on diagram), remove the present hoses, and connect the new water inlet hoses to the System 83 Plus (see "M").

2. Screw the GERMICIDE HAND PUMP ASSEMBLY (#11011) (see "Q") into a fresh gallon of germicide (see "P"), and connect the hand pump adapter to the water inlet hose(s) (see "K"). (Use a Y connector (see "Q") on the hand pump assembly if you are disinfecting the hot and cold black fill lines (see "K") to the System 83.) **NOTE:** Follow hospital policy on the handling of germicide/cidexOPA/disinfectant.

3. Plug the electrical line cord from the ***System 83 Plus™ (Washer/Disinfector)*** into the wall receptacle (see "O"), and turn the computer switch "ON". Return to the operating screen. If not familiar with the standard operation of the system, please locate the operator instructional manual or call ***Custom Ultrasonics, Inc.*** (215-364-1477) for assistance.

   I. Press **"WASH"** only using the keyboard. If machine is equipped with a rinse hand sprayer (see "N"), turn on the rinse switch. To keep hand sprayer open during this procedure place a rubber band around the spray nozzle handle (see "N") and place the nozzle handle in the processing chamber. Duplicate for a dual system.

   II. Hand pump ¾ of the fresh gallon of germicide (see "P") into the ***System 83 Plus™ (Washer/Disinfector)***. Confirm that the chemical has passed through the water inlet(s) and hand sprayer(s) into the processing chamber. As the chemical is passing through the hand sprayer handle unwrap the rubber band and return handle back to holder. Turn the rinse switch "OFF" (if equipped) and the computer "OFF". Pump the hand pump until resistance is felt.

   III. Follow manufactures recommendation of the germicide on how to achieve sterilization or high level disinfection.

4. Upon completion:

   I. Turn the computer switch "ON". If not familiar with standard operation of the system, please locate operator instructional manual or call ***Custom Ultrasonics, Inc*** (215-364-1477) for assistance. Select **WASH** only using the keyboard, as indicated on screen. Pump the remainder of the germicide from the gallon container.

   II. Disconnect the germicide hand pump assembly from bottle and connect the water inlet hose(s) (see "K") from the ***System 83 Plus™ (Washer/Disinfector)*** to the output of the sterilized cleared 0.1 micron bacteria filter(s) assembly (see "I1"). Connect the water filter supply inlet hose(s) (see "B") from the wall valve (see "A") to the input of the 5 and/or 25 micron pre-filter(s) (see "F1").

   III. Slowly turn the water valve(s) "ON" and allow the water to trickle into the 0.1 micron filter canister until the 0.1 micron filter is submersed in water. Failure to allow the water to trickle into the housing containing the 0.1 micron filter could cause damage to the filter. At this point, the valves can be opened to capacity. Adjust water temperature (to 110° degrees F) using hot and cold water valves (see "A") and a thermometer. The machine will now run a wash rinse cycle, which should take about 7 minutes. During the fill for the rinse phase turn on the rinse switch and spray the rinse nozzle (see "N") into the processing chamber until the machine stops filling. Allow the system to complete the wash rinse cycle. The operator may now use machine.

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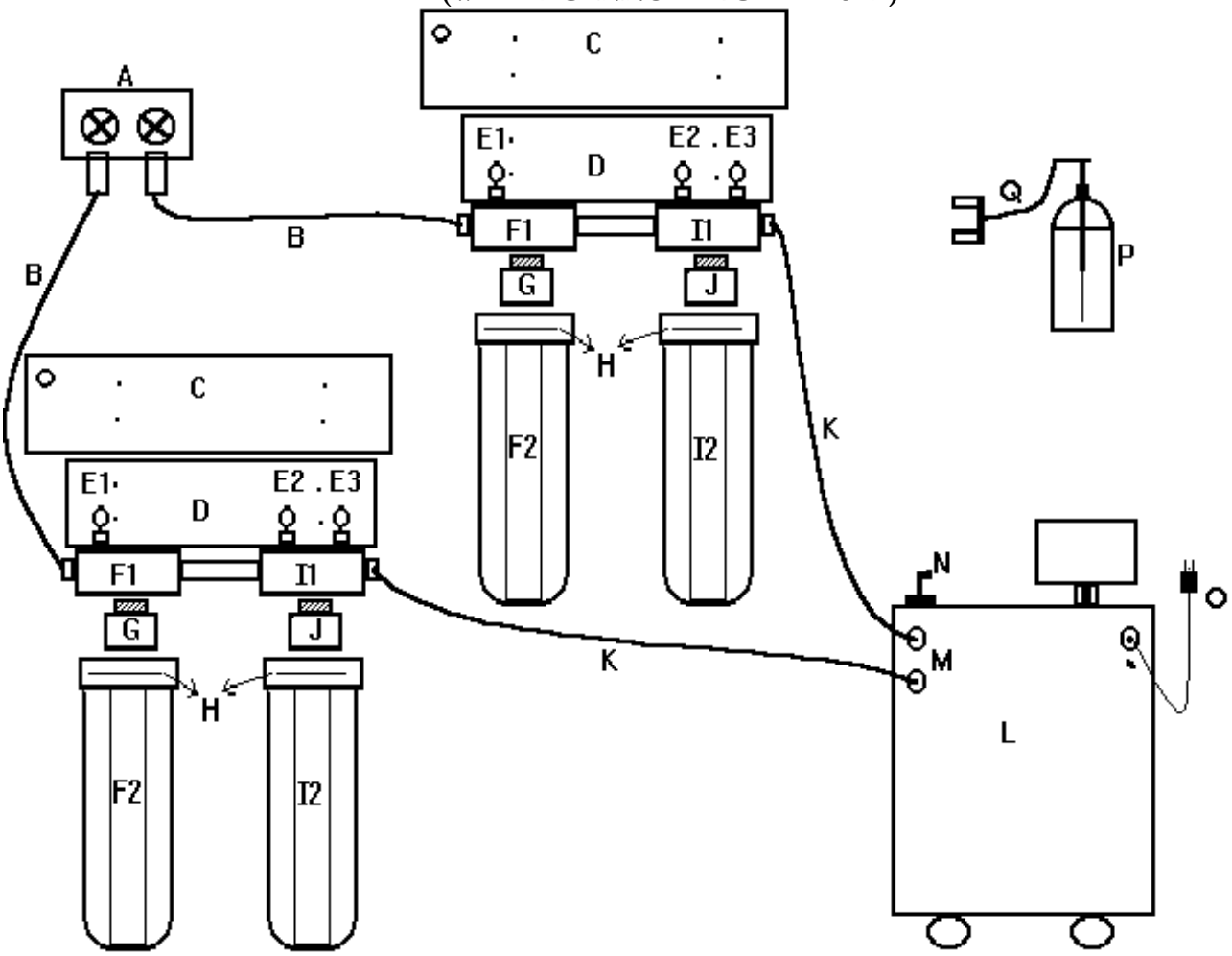
HOT & COLD FEED LINES THROUGH FILTERS TO *SYSTEM 83 PLUS™ (WASHER/DISINFECTOR)*

(WATER CANNOT EXCEED 115° F)



A) Hot and cold water valves

B) Water supply hose(s) from wall to 5 micron canister

C) White wall mount bracket

D) Aluminum frame bracket

E1) Pressure gauge for inlet of 5 micron canister

E2) Pressure gauge for inlet of 0.1 micron canister

E3) Pressure gauge for outlet of 0.1 micron filter canister

F1) Upper canister of 5 micron filter

F2) 5 micron filter canister

G) 5 micron filter

H) 0-ring for canisters

I1) Upper canister of 0.1 micron filter

I2) 0.1 micron filter canister

J) 0.1 micron filter

K) Water hose(s) from filter assembly to machine inlet

L) *System 83 Plus™ (Washer/Disinfector)*

M) Water inlet(s) of machine

N) Hand spray nozzle

O) Electrical plug

P) Fresh activated germicide

Q) Germicide hand pump

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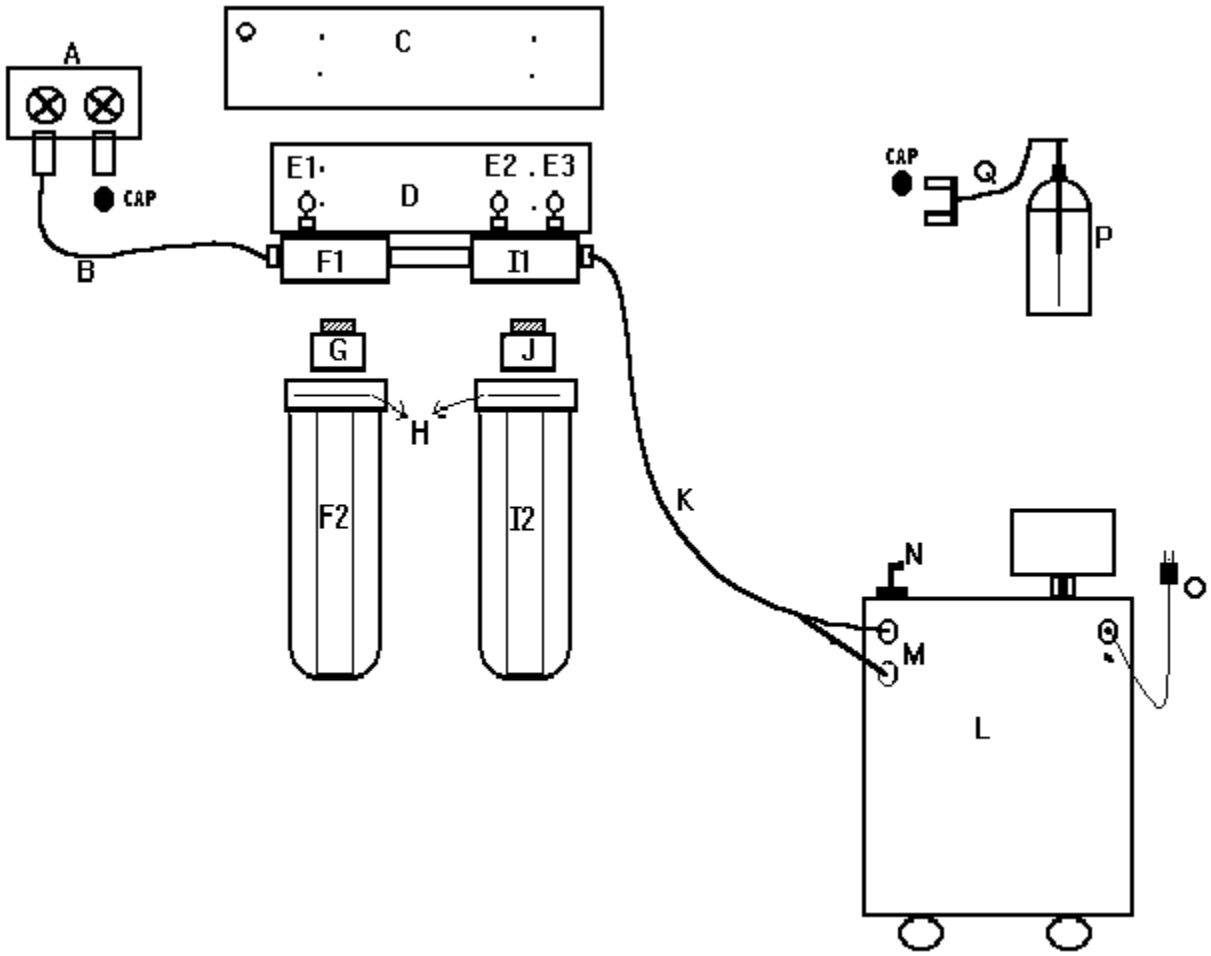
HOT FEED LINE THROUGH FILTERS TO *SYSTEM 83 PLUS™(WASHER/DISINFECTOR)*

(WATER CANNOT EXCEED 115° F)



A) Hot and cold water valves

B) Water supply hose(s) from wall to 5 micron canister

C) White wall mount bracket

D) Aluminum frame bracket

E1) Pressure gauge for inlet of 5 micron canister

E2) Pressure gauge for inlet of 0.1 micron canister

E3) Pressure gauge for outlet of 0.1 micron filter canister

F1) Upper canister of 5 micron filter

F2) 5 micron filter canister

G) 5 micron filter

H) 0-ring for canisters

I1) Upper canister of 0.1 micron filter

I2) 0.1 micron filter canister

J) 0.1 micron filter

K) Water hose(s) from filter assembly to machine inlet

L) *System 83 Plus™(Washer/Disinfector)*

M) Water inlet(s) of machine

N) Hand spray nozzle

O) Electrical plug

P) Fresh activated germicide

Q) Germicide hand pump

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DISINFECTING DETERGENT LINE

When changing the detergent bottle you must High Level Disinfect the detergent line(s) with a disinfectant chemical. For the required high-level disinfection soak time read the label on the bottle. Prior to performing the steps below, unscrew the detergent bottle from the pump assembly. In a one gallon container filled half way with chemical, connect it to the pump assembly. The following steps will be performed on the computer in the service program:

STEP 1: The entire system is turned "On" by opening front door of unit and engaging On/Off switch on CPU located in lower right hand corner of the machine. Allow the computer to perform the "Boot Up" procedure. When the computer is ready, a gray MASTER MENU screen will appear.

STEP 2: Red highlighted letters on menu are the activation keys. Hold down the ALT key and press the C key. Press the down arrow key and highlight SERVICE, press Enter. A blue selection bar will appear on the bottom.

STEP 3: Use arrow key and highlight DIGITAL I/O. Press Enter. A component screen will appear (see below) the highlighted cursor will be located on 1-1. This cursor is controlled by the arrow keys.

		Bay Outputs 1 2 3 4	**Bay Inputs** 1 2 3 4	
Ultrasonics	1	O O O O	O O O O	1 flow
Drain pump	2	O O O O	O O O O	2 float
Drain sol.	3	O O O O	O O O O	3 safety
Water in sol.	4	O O O O	O O O O	4 lubrication
Circulating pump	5	O O O O	O O O O	5 water channel
Disinfectant pump & sol.	6	O O O O	O O O O	6 reservoir pump
Disinfectant feed sol	7	O O O O		
Disinfectant return sol.	8	O O O O		
Residual drain pump & sol.	9	O O O O		
Air pump & sol.	10	O O O O		
Lube pump and sol; **(83 det)**	11	O O O O		

STEP 4: To activate the detergent pump, highlight the circle next to number 11 detergent 83 and press the SPACE BAR. Allow the chemical to be pumped into the round processing chamber. Once the chemical is coming through the detergent line, de-activate the component by pressing the SPACE BAR.

STEP 5: Allow the chemical to sit in the detergent lines for the minimum time required to achieve high-level disinfection.

STEP 6: On completion of the soak time remove the bottle filled with chemical from the pump assembly and place a new bottle of detergent on to the pump assembly.

STEP 7: To activate the detergent pump, highlight the circle next to number 11 Detergent 83 and press the SPACE BAR. Allow the chemical to be pumped out of the detergent lines into the round processing chamber. Once the detergent is coming through the detergent line, de-activate the component by pressing the SPACE BAR.

STEP 8: To remove any liquid out of the processing chamber before processing a scope, move the cursor up to number 9 residual drain pump & sol. and allow it to run until the liquid is no longer present. Next, press the space bar a second time to deactivate the residual drain pump.

STEP 9: To exit service program, reset computer.

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DISINFECTION OF INTERNAL AND EXTERNAL ALCOHOL PURGING ASSEMBLY

The following procedure must be performed to achieve disinfection every 3 months during preventive maintenance.

EQUIPMENT:

60CC SYRINGE
GRAY ALCOHOL SYRINGE ADAPTER (PT#18030)
CONTAINER OF STERILE WATER
ONE GALLON CONTAINER OF ACTIVATED GLUTARALDEHYDE AT OR ABOVE ITS MEC OF 1.5%

---

1. **Completely fill** the entire alcohol adapter and attached 60cc syringe with 1.5% activated Glutaraldehyde at or above its MEC of 1.5% (or an equivalent FDA-cleared disinfectant/sterilant).

2. Insert alcohol adapter /syringe into alcohol port located on top of machine. Inject disinfect until it is seen flowing into process chamber through adapters.

3. Steps 1 and 2 may have to be repeated until disinfectant is passing through the adapters.

4. Allow disinfectant to remain in contact for at least 10 hours for sterilization (or 45 minutes for high level disinfection) maintaining at 20°C > to < 25° C.

5. **Drain disinfectant from the alcohol line after at least 10 hours of exposure.** Introduce sterile water into the alcohol line in the same manner as the disinfect step. In order to rinse disinfect from the alcohol line. Repeat sterile rinse of alcohol line three times.

Any problems or questions please contact ***Custom Ultrasonics, Inc*** at 215-364-1477

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